Exhibit C

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 U.S. DISTRICT JUDGE JOSEPH R. GOODWIN

GENERAL DEPOSITION of DEBRA L. FROMER, M.D., pursuant to Notice, on the 29th day of March 2016, at RIKER, DANZIG, SHERER, HYLAND, PERRETTI, LLP, 500 Fifth Avenue, New York, New York, commencing at 9:00 a.m.; before DANA N. SREBRENICK, a Certified Court Reporter, a Registered Realtime Reporter and Notary Public within and for the State of New York.

APPEARANCES:

On behalf of Plaintiff:
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EXHIBITS

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MS. FITZPATRICK: We'll mark as 1, the depo notice.
(Exhibit Fromer 1, Notice to Take Deposition of Debra L. Fromer M.D., marked for identification.)
MS. FITZPATRICK: We can mark as 2 the TVT-O general report.
(Exhibit Fromer 2, TVT-O General Report, marked for identification.)
MS. FITZPATRICK: The Prolift report will be number 3.
(Exhibit Fromer 3, Prolift Expert Report of Debra L. Fromer, M.D., marked for identification.)
(Exhibit Fromer 4, Curriculum Vitae of Debra L. Fromer, M.D.'s, marked for identification.)
MS. FITZPATRICK: Let me mark the February 2016 reliance list as 5.
(Exhibit Fromer 5, February 2016 Reliance List, marked for identification.)
MS. FITZPATRICK: This is 6.
(Exhibit Fromer 6, Exhibit B to General Expert Report of Debra L. Fromer, M.D., marked for identification.)
DEBRA L. FROMER, M.D., doing business at 360 Essex Street, Hackensack, New Jersey 07601, having first been duly sworn by the Certified Court Reporter of the

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State of New Jersey was examined and testified as follows:

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EXAMINATION BY MS. FITZPATRICK:

- - -

Q Good morning, Dr. Fromer. My name is Fidelma Fitzpatrick. Have you been deposed before?
A Yes.
Q So we'll go through a series of questions. We're going to try to get through it as quickly as possible today. If at any point you need a break, you need to stretch your legs, just let me know and I'll be happy to take a break. Otherwise, we'll just plow right through until we get to the end.
And if you at any point in time don't understand something that I've asked or don't understand something that I've said, please let me know. Otherwise, I'll just assume that you understood the question and we can move on.
Today -- actually, last night your counsel provided me with a new copy of your CV. Do you have that in front of you? It's marked as Exhibit 4.
A It might be here.
Q Okay.
A You can mark off the original.

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Q And we had previously been provided with a copy of your CV with the expert report that you generated in this case. And can you tell me what the difference is between your old CV that was provided with your report, and the CV that I was provided last night?
A I believe there's only one updated item and that is under presentations. So, the first presentation listed occurred, I'll say November, late November.
Q Okay.
A This was a lecture given to the department of OB/GYN.
Q And that was a lecture give at Hackensack University Medical Center?
A Correct.
Q And is that the only addition or change between the original CV that was provided to us in connection with your expert report and the CV that I was provided last night?
A Do you have the old -- the older CV, and I'll just double check and make sure that there --
Q I sure do.
A -- are no additional publications?
Yes, that's the only addition.
Q Great, thank you.
Now, you attended the University of

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Pennsylvania for your undergraduate, correct?
A Correct.
Q And Tufts University for medical school?
A Correct.
Q And you did your internship and residency at New York-Presbyterian Hospital?
A Correct.
Q Have you done a fellowship?
A No.
Q And what are your board certifications?
A I was certified in general urology in 2005. And then the year that the subspecialty certification for FPMRS came out, I sat for that board and passed. And so I became subspecialty certified in 2015.
Q And what you're talking about is female pelvic medicine and reconstructive surgery, correct?
A Correct.
Q And that was 2013 that you became certified in that?
A That's correct.
Q And you're not a gynecologist, correct?
A That is correct.
Q And you're not a urogynecologist, correct?
A That is correct.
Q Now, you're currently affiliated with

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Hackensack University Medical Center?
A Correct.
Q As well as the New York-Presbyterian Hospital/Weill Cornell Medical Center, correct?
A That is correct.
Q In your work, have you come across Dr. Jerry Blaivas?
A I have talked to him at meetings.
Q Okay.
A We have had conversations by phone regarding mutual patients.
Q Okay. And in connection with your work with the Cornell Medical Center, have you had any professional involvement with him beyond discussing patients?
A No.
Q And how many patients have you had with Dr. Blaivas?
A Mutual patients?
Q Mutual patients, yeah.
A I can only think of one in recent years and another one many years ago, maybe five or ten years ago.
Q Okay. Now, you're a member of the Society For Urodynamics in Female Urology, correct?
A That's correct.

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Q The American Urological Association?
A Correct.
Q The New York section of the American Urological Association?
A Correct.
Q The Kidney and Urology Foundation of America?
A Yes.
Q The International Continence Society?
A Correct.
Q The Society of Women in Urology?
A Yes.
Q And you're a reviewer for urology and urodynamics?
A Correct.
Q And on the editorial board of Canadian Journal of Urogynecology, correct?
A Correct.
Q Now, you have never written a peer-reviewed article or journal on polypropylene mesh, correct?
A That's correct.
Q And you've never written a peer-reviewed journal article on the Burch procedure, correct?
A Can you go back to the previous question you asked?
Q Uh-huh.

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A I did publish an article in the Canadian Journal of Urology.
Q Okay. And which article is that?
A If you look at our publications. So number 2, Techniques to Avoid Complications in Transvaginal Mesh Surgery.
Q Okay. And that was published in 2015?
A Correct.
Q Okay. And apart from that, is there any other peer-reviewed journal article that you have published on polypropylene mesh?
A No.
Q And you've never written about the Burch procedure, have you?
A No.
Q And you've never written about pubovaginal slings, have you?
A No.
Q And you're not an academic physician; you're a physician in private practice, correct?
A That's not correct.
Q Okay. You'll agree with me that you're not an expert in chemical engineering, are you?
A What do you mean by that?
Q Do you know what the field of chemical

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engineering deals with?
A Well, polypropylene mesh is probably one thing that chemical engineering may evaluate. However, I'm not a chemical engineer. I was not trained in chemical engineering, but I am very familiar with the usage of some things that chemical engineers may be looking at.
Q Okay. What type of polypropylene is used in the Prolift?
A What -- for example? What do you mean?
Q Do you know that there are different types of polypropylene?
A Well, the general -- the polypropylene that we use is monofilament large pore mesh that -- are you -- is there -- then I'm not familiar with the different --
Q Okay. You understand that meshes are made from polypropylene, correct?
A That is correct.
Q And that polypropylene is spun or woven or knit into the various meshes that are used for pelvic organ prolapse and stress urinary incontinence, correct?
A That's correct.
Q And so the basic polypropylene, before you get it to a mesh, do you know the different types of polypropylene that exist?
A No.

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Q Do you know anything about the antioxidants that are added to polypropylene as they're used in the Ethicon products?
A I have read about it in company documents.
Q What antioxidants are used in the Prolene products?
A I can't recall.
Q Have you had any training in that beyond reading company documents?
A No.
Q And you agree with me that you're not a chemical engineer by training?
A Correct.
Q And you're not an expert in pathology, correct?
A I'm not a pathologist. However, I grossly inspect polypropylene mesh after explantation or on reoperation.
Q Okay.
A And I have spent some time in the pathology lab looking at pathologic specimens.
Q Okay. Have you spent time in the pathology lab microscopically looking at explanted polypropylene meshes?
A No.

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Q Have you ever seen an explanted polypropylene mesh microscopically?
A Yes, I've seen images.
Q And are those images of patients that you removed it from?
A No. I've seen images in the literature.
Q Okay.
A And in lectures.
Q Now, you've actually removed polypropylene mesh from patients, correct?
A Correct.
Q Do you send that to a pathologist --
A Yes.
Q -- for examination?
A Yes.
Q And what do you look for in that examination? What do you request from the pathologist when you do that?
A I am not requesting anything specific. And generally, the pathologic reports are generally similar.
Q What do you mean by that?
A The typical findings that we might see in postsurgical specimens which might include scar tissue, inflammatory response.
Q Have you ever requested that the explanted

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mesh that you've reviewed be examined for degradation?
A No.
Q Beyond scar tissue and inflammatory response, what else do you feel are typical of the findings that you see in the pathology reviews of explanted mesh that you've removed?
And that was probably the most confusing question ever. So let me start that -- let me start that one all over again.
You testified that there were typical findings in explanted meshes that you had removed, correct?
A Correct. That are consistent with other postoperative specimens, not necessarily related to polypropylene mesh.
Q But they're present in the polypropylene mesh samples that you've removed, correct?
A Correct.
Q And you have seen their scar tissue and inflammatory response; that's what you had indicated, correct?
A Correct.
Q Is there anything else that you believe is typical for you to see in the pathology specimens that you -- from polypropylene mesh that you have removed?
A No. Usually they state that the polypropylene

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mesh is intact, grossly intact, and under the microscope intact.
Q Anything else?
A No. And also -- I mean, just as an aside going back to this question, one of the reasons why we do send the explanted meshes is -- is mostly for documentation that the mesh was, in fact, excised.
Q So, when you send it, you want to make sure that you got the mesh out, correct? That's what's in the specimen?
A Well, I know that the mesh is there.
Q Yes.
A But I want it documented for future purposes that the mesh was excised.
Q And you're not looking, at that point, at whatever particular disease processes or reactions that the body had to the mesh, correct?
A Correct.
Q And you're not looking to see what reaction the mesh had to the body, correct?
A What reaction the mesh had to the body?
Q You're not looking to see whether it degraded?
A Well, degraded the body? What do you mean?
Q The mesh degraded, sorry.
When you send it to pathology, you're not

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looking to see whether the mesh degraded in the body, correct?
A That is correct because I don't believe it to be significant.
Q That's because you don't believe it to be significant, but you never actually looked for that pathology, correct?
UNIDENTIFIED SPEAKER: Objection.
A That's correct.
BY MS. FITZPATRICK:
Q All right. And --
A However -- however, like I said, they usually do mention that the mesh is intact.
Q Okay. And you believe that mentioning it intact means it has not microscopically degraded in any level?
A That the mesh is there, physically present.
Q Okay. But you're not trained in pathology, correct?
A I did not do a fellowship training in pathology.
Q Okay. Now, talking about your clinical practice, how many slides have you microscopically examined of patients from whom you have removed mesh?
A How many slides have I examined in patients?

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Q Uh-huh.
A None.
Q Okay.
A And I also don't -- I remove mesh maybe once, twice a year, so it's not a very frequent occurrence.
Q How often have you removed mesh total in your career?
A This is an estimate?
Q Yes.
A I would say between 10 and 20 cases in my career.
Q And have you sent all of those 10 to 20 cases to a pathologist for review?
A Yes.
Q You agree with me that you're not a trained expert in polymer chemistry, are you?
A I'm not a trained expert in polymer chemistry.
Q And you've never done bench research on polypropylene, have you?
A No.
Q And you've never done any lab research on polypropylene, have you?
A No.
Q You agree with me that you're not a biomaterials specialist?

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A I'm not a biomaterials expert. However, as I've said before, having implanted over a thousand women with polypropylene mesh, I have a lot -- a great amount of experience in the usage of polypropylene mesh in the clinical setting.
Q Okay. But I just want to make sure, for the purposes of this deposition, that I'm deposing you on what you're an expert in.
We're here to talk about the clinical implications of using polypropylene mesh, correct?
A That's correct.
Q And you're not here to talk about the properties of the polypropylene mesh itself outside of the body?
A You're saying invitro?
Q Outside of the body.
A Correct.
Q And you're not here to talk about the biomaterial property of the polypropylene that is used in Prolene mesh in any way, are you?
A I'm not, not in the extent of my handling it for surgical purposes.
Q Okay. And you're not here to talk about the effect of antioxidants on the polypropylene that is used in the Prolift and the TVT-O, correct?

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A Not to the extent that it affects my clinical usage of it.
Q Do you believe that polypropylene creates a foreign body reaction when implanted?
A I believe that polypropylene creates a reaction that is typical of any implant in the human body, which is -- and also occurs in any surgical procedure that we do on patients, which is basically an acute inflammatory response that then settles down to a clinical physiologic response.
Q Do you believe that polypropylene can create a chronic foreign body reaction when implanted into the pelvis?
A Again, I believe the mesh incorporates into the body. I believe it is a foreign body. I believe that we all react to foreign bodies in a very similar and reproducible way, and that settles into a chronic, but clinically not pathologic, reaction.
Q You're not an expert on warnings, are you?
MS. KABBASH: Objection.
A I have great experience in reading warnings, in reviewing warnings, in reviewing the medical literature as it relates to the warnings in -- in -- particularly with respect to this litigation, in reviewing the surgeon's monograph, in reviewing the

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IFUs. I've had experience in developing warnings for pharmaceuticals. So though I may not be an expert in dealing with the FDA on a direct basis, I do have a lot of experience with warnings.
BY MS. FITZPATRICK:
Q What IFUs have you written?
A I have not written any IFUs. However, I was involved in developing warnings for a drug called Toviaz made by Pfizer.
Q And what does Toviaz do?
A Toviaz. It's T-O-V-I-A-Z. It's an anticholinergic in the treatment of overactive bladder.
Q And when you said you were involved in the development of warnings for that drug, can you tell me exactly what it was that you did?
A Sure. I was invited to participate in a consultation group in the development of a package to be given to patients as samples for the drug, and included in that was warnings and side effects.
Q Okay. So you were asked by Pfizer to get involved in this consultation group, correct?
A That's correct.
Q And am I correct that Pfizer was interested in your clinical experience in using this particular drug?
A No. So the drug was not available at that

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time. The drug was in development, and they were developing the packaging for the samples.
Q What did you contribute to the warnings on that packaging?
A It was a while ago, so I can't specifically remember what I said or what my recommendation was. However, side effects and warnings were part of the conversation.
Q At the time that you did this, did you know what the side effects of the drug were?
A Well, we know what the side effects of all anticholinergics are, and we were presented with data from the company.
Q Yeah. So at that time, you didn't have any clinical experience on your own in using that drug, correct?
A That's correct.
Q And so you were relying on the information that Pfizer gave you about the potential side effects from that particular drug, correct?
MS. KABBASH: Objection.
A The studies that were performed before the launching of the drug.
BY MS. FITZPATRICK:
Q Okay. And those were studies that were funded

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by Pfizer?
A I'm not sure.
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q And I want to know what involvement you specifically had in developing the warnings for Toviaz.
A Honestly, I don't remember the details of the conversation with regards to warnings or even with regards to the development of the materials that were given to the patient. It was eight to ten years ago, I would say.
Q And did this consultation group have anything to do with drafting the actual instructions for use that would go to physicians?
A I don't remember.
Q So, apart from that experience you had eight to ten years ago, what other experience have you had in actually writing or drafting warnings for use with either a medical device or a pharmaceutical?
A That was it.
Q Do you read the IFUs that come with the products and drugs that you're using with your patients?
A Yes.
Q Do you consider them an important part of the information that you, as a physician, have to understand

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the risks and benefits of a particular medical device?
A No.
Q Not important to you at all?
A As I said, I read them. I've read them once, generally, prior to using any new product.
However, there's nothing in there that I don't already know. There's nothing novel that most surgeons, who are doing these surgeries regularly, are not already trained on and don't already know.
Q But you would agree with me that an instruction for use should be complete and accurate, correct?
A Again, I mean, I believe that surgeons should not be relying on an IFU to know what the risks, benefits, and how to use the products are. I believe that they should have hands-on training and not learn from a piece of paper how to do a surgery and what the complications and risks are.
Q And in addition to that, I mean there's a reason that there's an IFU that goes along with a medical device, correct?
A You know --
MS. KABBASH: Objection.
A -- I mean, I've always understood that to be something that the FDA has required. I've understood it

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to be something that is key in litigation. However, in reality, in clinical practice, I -- I just don't think it's as relevant as training and reading the literature and attending conferences.
BY MS. FITZPATRICK:
Q So let me take you back though.
Understanding that you believe that training and reading the literature and attending conferences are an important part of a physician's job; so we've established that.
But I want to go back to this question about the IFU. You understand, don't you, that the IFU accompanies a medical -- there's a reason that a medical device has an IFU with it, correct?
MS. KABBASH: Objection.
A Again, the -- there may be a reason, but I do not, in my personal opinion, believe that the reason is to train doctors on how to do the surgery and to know the complications.
BY MS. FITZPATRICK:
Q Okay. Then that's fine, but there's a reason for it regardless of whether it's to train, correct?
A Well, I can assume so, but I'm not -- you know, I -- again, the reason may not make complete sense to me.

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Q Well, let me ask you it in a different way.
You'll agree with me that the IFU is one way that a medical device manufacturer can communicate what it knows about the risks and benefits of its products to a physician, correct?
A Sure.
Q And you'll agree with me that even if you've read the literature and even if you've gone to training and even if you've gone to conferences, that a medical device manufacturer also, separate and apart from that, has an obligation to tell you, as a physician, what it knows about the risks and benefits of its products, correct?
A Correct.
Q And so even though you may not rely on it exclusively, it is a source of information and the way that a medical device manufacturer directly communicates with the physician, correct?
A Correct.
Q And in doing so and having that communication, you'll agree with me that a medical device manufacturer has the obligation to be truthful and honest about the risks and benefits associated with its products, correct?
A An obligation to whom?

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Q The physicians.
A I don't necessarily believe that. Again, first of all, it's my --
Q You don't think they have to be truthful and honest?
A Well, I didn't say they have to be dishonest. I don't believe that they have to include everything that a physician needs to know to operate on a patient.
Q That wasn't my question though.
So I'm not asking you whether they have to include everything that a physician needs to know to operate on a patient. All I'm asking you is: In this method of communication between a medical device manufacturer and a physician, such as yourself, you believe that a medical device manufacturer has an obligation to be truthful and honest about the risks and benefits associated with its product in the IFU, correct?
A Some of the risks and benefits, yes.
Q What risks and benefits don't they have to tell you?
Well, let me ask you this: What risks and benefits don't they have to be truthful about?
MS. KABBASH: Objection.
A I don't believe -- I'm not sitting here saying

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that a company should be lying to physicians or doctors.
BY MS. FITZPATRICK:
Q So we can agree that they shouldn't be lying to --
A They should always be honest, correct. We're onboard with that.
Q All right. That's all I was getting to.
And if a medical device company knows of a risk inherent or specific to its medical device, you believe they have an obligation to tell the medical community about that, correct?
A If it is inherent to the device, correct.
Q Now, you've never designed a medical device, have you?
A I've been involved in the development of a medical device.
Q Have you ever designed a medical device?
MS. KABBASH: Objection.
A In terms of patenting it myself? Can you be more specific?
BY MS. FITZPATRICK:
Q Well, let me go back and ask you this: You have -- let me get your exact language here because I don't want to misstate you.
What has your involvement been in the

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development of a medical device?
A I consulted with AMS regarding the development of their Elevate product.
Q And when was that?
A Well, probably about five years ago.
Q And what was your role?
A I used one of their novel devices that was not yet launched on a cadaver to assess its use and give my opinion on how it can be improved or whether it needed to be improved.
Q And was that the product that eventually became the Elevate --
A Yes.
Q -- for the pelvic organ prolapse?
A Yes.
Q And what advice did you give AMS on how the Elevate product could be improved?
A I can't remember. I'm sure I had an opinion on the shape of the trocars and the mesh itself, but I can't recall specific details.
Q And when did AMS approach you about this?
A That was in the months prior to my visit.
Q When would that have been?
A I'm sorry. Prior to my -- I'm sorry.
Q Okay.

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A Let me go back.
Q I thought I missed something.
A I -- I -- my visit to AMS was however -- you know, prior to the launch of Elevate. And I'm estimating five, six years ago. And they contacted me to make that visit in the months prior to my actual visit. So I just don't remember the dates of it.
Q And how much time did you spend giving AMS feedback on the Elevate product before it was launched?
A Three or four hours.
Q Were you paid for your time?
A Yes.
Q And why did AMS select you?
MS. KABBASH: Objection.
A I can't answer for them, but I suspect because they knew that I had a high volume of patients with prolapse and pelvic floor disorders.
BY MS. FITZPATRICK:
Q And had you been using AMS products at the time?
A Yes. I think I was using some of their products.
Q And which products were you using?
A At that time, Apogee and Perigee were available. They had slings. However, I wasn't using

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them as much as the Gynecare products.
Q Okay. When did you stop using AMS products?
A I haven't.
Q Which products do you currently use?
A Anterior Elevate and MiniArc.
Q Do you use any other manufacturer's products besides AMS?
A Yeah, I use the Gynecare products of slings.
Q Sorry. I was taking that for granted since that's what we're here about that. Anything besides Gynecare and AMS?
A I, on occasion, use the Capio, which is a Boston Scientific product for native tissue repairs.
Q Anything else?
A That's it.
Q Let's talk about your reports in this case.
You prepared actually four reports, correct?
You prepared the report on the Prolift that is marked as Exhibit 3, correct?
A Yes. I provided you a general report on Prolift.
Q Okay. And you also provided a general report on the TVT-O, correct?
A Correct.
Q And did you also provide a general report on

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the TVT retropubic?
MS. KABBASH: Not in the MDL Wave 1.
MS. FITZPATRICK: Not in the MDL Wave 1?
MS. KABBASH: Right.
BY MS. FITZPATRICK:
Q But you have provided a report on the TVT retropubic before, correct?
A Correct.
Q And you've been deposed on that particular product?
A Correct.
Q And that was in connection with the New Jersey Ethicon litigation, correct?
A Correct.
Q And then in addition to that, you provided one case-specific report in Mrs. Sacchetti's case that we'll discuss later, correct?
A Correct.
Q So those are the only reports that you have generated for Ethicon to date in any litigation?
A That's correct.
Q Okay. How much time did you spend reviewing materials in order to write your Prolift report?
A I have a little note I prepared for that question. So the counsel has all the numbers up until

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March --
Q Okay.
A -- that they can provide you with a breakdown.
MS. KABBASH: I have invoices for the time she spent in Wave 1.
MS. FITZPATRICK: Okay. Super. Let's start with that one. I'll get those marked.
MS. KABBASH: These are three copies each. There's a payment in February and a payment in March.
MS. FITZPATRICK: Okay. Great, okay.
So let's go ahead and mark these as Exhibit 7?
MS. KABBASH: Yes.
MS. FITZPATRICK: Yeah, 7.
MS. KABBASH: I think they're collated by three copies, so --
MS. FITZPATRICK: Okay.
MS. KABBASH: -- there's three. You know, I should take one for myself.
MS. FITZPATRICK: Yeah, I got three. You can have one. I'll keep one.
So why don't we mark the February 3, 2016, and the March 3, 2016, invoices as 7.
(Exhibit Fromer 7, February 3, 2016 and March 3, 2016 invoices, marked for identification.)
BY MS. FITZPATRICK:

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Q So what I've put in front of you, as Exhibit 7, are a series of invoices. The first one dated March 3rd, 2016, and that looks like that involves primarily the preparation of your TVT-O report; is that correct?
A These are for dates in January, for work in January.
Q Just looking through the description of services, all relate to the TVT-O, correct?
A Correct.
Q And then you've got a second invoice that looks like the work that you did in February?
A Correct.
Q And if I'm just quickly reviewing this, it looks like this is work on the Prolift general report, the TVT-O general report, and Mrs. Sacchetti's case-specific report, correct?
A That's correct.
Q And are these two invoices an accurate reflection of the work that you have spent on the Wave 1 cases through the end of February?
A Yes.
Q So I'm not going to do it now, but I could go through and add up the hours that you spent on the Prolift general report and that'd be pretty accurate for preparation?

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A Yes.
Q Since you've submitted these invoices, have you done additional work for Ethicon?
A Yes.
Q And that would be starting in March?
A Correct.
Q Can you tell me what work you have done for Ethicon in March?
A Sure. So, for work on the Sacchetti report, it was 9.2 hours.
Q Uh-huh.
A For deposition preparation, it was nine and a half hours plus a full day of prep with counsel and then today's full day.
Q And today's, okay.
So the 9.25 hours, is that spent on actually drafting the report in Mrs. Sacchetti's case?
A Yes. Drafting the report, possibly re-reviewing medical records, editing the report, revising the report, finalizing the report.
Q Okay. And then you said that you spent 9.5 hours on depo prep. Can you tell me what you did to prepare for your deposition?
A Sure. I reread key medical records. I reread some of the pertinent articles. I reread my reports.

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And then for the full day of dep prep, I was with counsel.
Q Okay. And who did you meet with?
A Maha.
Q And when was that?
A Sunday.
(Whereupon, a brief discussion is held off the record.)
BY MS. FITZPATRICK:
Q So, about how many hours did you spend on Easter Sunday preparing for the deposition?
A So with Maha, we were working from around 9:00 in the morning until around 4:30 in the afternoon, and then I continued my work into -- later into the evening.
Q Did you do anything else to prepare for your deposition besides reviewing the medical records, the articles, the reports, and then spend time with counsel preparing?
A Yeah. So I think that you were provided with a couple of updated articles. You got an updated list of articles that were reviewed. And in reading the case-specific reports, I did do a little more literature search.
Q Okay. So let me go there.
So we have marked --

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MS. KABBASH: Before you do, I just want to add one thing to make sure you don't have inaccurate information on the transcript. You asked her before: Are these all the reports you've ever done? I think it was a broad question. I just want to make sure you're also aware, last year she did reports in two New Jersey case-specific matters called Cannon and Nemcek.
MS. FITZPATRICK: Okay.
MS. KABBASH: She ultimately was not deposed on them because the cases were dropped out of the trial selection and so she was not deposed on them.
MS. FITZPATRICK: Okay. Thank you.
MS. KABBASH: I just didn't want that to result in an incorrect transcript.
MS. FITZPATRICK: Are those case-specific reports only?
MS. KABBASH: Yes.
MS. FITZPATRICK: The general portion of that?
MS. KABBASH: Well, she had the general TVT report in New Jersey which she told you about.
MS. FITZPATRICK: Okay.
MS. KABBASH: In addition to that, they were case-specific in those two cases which were TVT retropubic cases.
MS. FITZPATRICK: That's Cannon, and what was

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the other one?
MS. KABBASH: Nemcek, N-E-M-C-E-K.
MS. FITZPATRICK: Okay. Thank you. I appreciate your clarifying that.
THE WITNESS: Bad memory.
MS. KABBASH: Sometimes they don't mind if we testify if it's short circuit things.
MS. FITZPATRICK: Yeah. We can spend a half an hour trying to figure that out and getting to the bottom of it.
BY MS. FITZPATRICK:
Q So let me take a look at some things here. So we have a list of materials that were updated on March 28th, 2016, and I just received that last night. And previous to that, I have a list of materials reviewed from February 2016. So can you help me out because I haven't had time before this deposition to compare?
A Sure.
Q Can you tell me what's on your March 28th that wasn't on your February 2016?
A Sure. Can you hand me the old one that you have, and I can --
Q Sure.
MS. FITZPATRICK: We should have them marked as 5 and 6.

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A If you give me a pen, that might help as well.
MS. FITZPATRICK: Do you mind if I just take a very quick break?
MS. KABBASH: Yes. Go for it.
(Whereupon, a brief recess is taken.)
A See it looks -- I found five articles that were not on the old list that are on the new list that I can easily identify. However, I'd have to really go through the list to identify the new ones, the other new ones.
BY MS. FITZPATRICK:
Q Okay. So it looks like if I -- let me make sure that I've got the right thing.
So it looks like the medical literature in your initial -- well, let me ask you this: Did you take anything off of your reliance list?
A No.
Q So you had 318 articles on your February reliance list and you have 336 that are on your current?
A Correct.
Q So we've added 18. Eighteen articles have been added to the medical literature; is that right?
A Right.
Q And who picked those articles?
A The five that I have, I did.

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Q Okay.
A The other ones, I'm still trying to search where they are. And I can't remember which ones they are, specifically, off the top of my head. So, what I'm doing is I'm going line by line to see where they're off, to see where they were added.
Q So you have in front of it, it looks like a piece of paper in front of you with some notes on it?
A Yes.
Q Can you tell me what that is?
A Sure. These are a list of articles reflecting patients who have had hysterectomy for pelvic pain and dyspareunia, and what their outcomes were afterwards and whether their deep dyspareunia and pelvic pain continued after their hysterectomy done for endometriosis, for example. Some of them comment on persistent endometriosis or de novo endometriosis after hysterectomy.
Q Okay. And of these are articles that you found yourself, that you've added to the reliance list. Now, who actually generated this reliance list? Did you generate it or did counsel generate it for you?
A Counsel did.
Q So did you provide these five articles to counsel for inclusion in this list?

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A Yes.
MS. FITZPATRICK: Could we go ahead and -- I don't know if you want to keep the original and we'll get a copy of it or we can just mark the original. Whatever you want to do.
MS. KABBASH: I thought you might ask for that. Not to volunteer, but she has other notes she might --
MS. FITZPATRICK: Great. Can we just --
MS. KABBASH: Okay.
MS. FITZPATRICK: I'm going to ask for them.
THE WITNESS: Do you want all of them?
MS. KABBASH: You're going to ask for them?
MS. FITZPATRICK: Do you have a copy?
MS. KABBASH: I have copies. You keep what you want.
THE WITNESS: In the meantime, I'm doing it.
MS. FITZPATRICK: No. These are notes related to the general report, correct, as opposed to --
MS. KABBASH: That's a good question.
MS. FITZPATRICK: Are these related to Mrs. Sacchetti at all?
THE WITNESS: Okay. So here's another one.
MS. KABBASH: Let me see if there's anything outwardly -- it's all medical literature. There may be

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some medical literature in here that's more pertinent to -- may be pertinent to Sacchetti because of her --
MS. FITZPATRICK: Okay. So, for example, the endometriosis.
THE WITNESS: And also, I just found a duplicate. It looks like somebody repeatedly added the da Silveira article, so that adds another one.
It's just in the new one, it looks like it was already one that was already in my reliance list. It's duplicated.
MS. FITZPATRICK: Okay.
THE WITNESS: So it makes it look like there's an extra article in there, but there's not.
MS. FITZPATRICK: Okay. Let me go ahead and let me mark these notes as Exhibit 8.
(Exhibit Fromer 8, List of articles, marked for identification.)
BY MS. FITZPATRICK:
Q Let me put that in front of you and ask you if you can just identify what those are for the record.
A Okay.
Q And can you identify and tell the court reporter what those documents I've just handed you are?
A Okay. So the first page is the page I just described to you. The patient -- the list of articles,

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my notes on these articles, talking about women with endometriosis who had undergone hysterectomy and patients who had persistent pain after hysterectomy.
The next page are a list of articles regarding TVT-O and neurovascular or leg pain.
The next page is a list of articles for TVT-O, randomized controlled trials, and metaanalysis.
The next page is my notes on the Maher/Cochrane review on prolapse repair from 2016.
The next page are my notes on articles where symptomatic mesh retraction was discussed.
The next page is on de novo dyspareunia in patients after mesh repairs for prolapse. And there's a little note on the back of that page reflecting one more article.
And the next page is exposure and erosion data. This is for Pro -- this is for Prolift and other transvaginal mesh for prolapse repair. The back of that page it continues, and then I have notes on just general complications.
Q Okay.
A And the last page is the March breakdown, that we earlier discussed, for the invoice.
Q Thank you.
So I think you were correcting me that there's

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probably actually 17 articles that were added to this list. You didn't bring a copy of those articles with you today, did you?
A I didn't, but I think counsel is supposed to have it on a flash disk, but I think the wrong one came. I'm sure you were alerted to that.
MS. FITZPATRICK: I don't know if I'm going to ever need to do this, but until I have a chance to look at what those 17 articles are and look through them, I'm obviously not going to be able to ask her any questions on it. So I'm going to reserve a little bit of time. If we do come back, I'm going to do it by phone.
But I need to do that since I haven't had an opportunity to take a look through those articles to question her today.
MS. KABBASH: I'll object to that request on the record, but we can save that for another time.
MS. FITZPATRICK: Sure.
BY MS. FITZPATRICK:
Q In addition to the additional medical articles that you added, are there any other materials that you've added to your reliance list between February 2016 and March 28th, 2016?
A I don't believe so. I think that covers it.
Q Did you add any additional Ethicon documents

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to the list?
A I don't believe so.
Q Okay. Any additional medical records or deposition transcripts to the list?
A No.
Q Okay.
A So if you want me to -- I found a few of the articles for you. Do you want me to --
Q Sure. If you could --
A -- stop that or just keep --
Q No.
A -- doing what I'm doing?
Q I would love it if you can tell me what those are, and you can identify them by number for me --
A Okay.
Q -- but I don't want to use too much of your time. You have limited time. I don't --
A Okay. Hopefully it won't take too long.
(Reviewing documents.)
Q How much longer do you think it will take you?
A Right now, I'm on 199.
Q You know what --
A Do you want me to stop?
Q I do. If you can tell me right off the bat which ones you know.

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A Okay. So I'll go through the ones that I have so far.
Number 62. Like I said, number 71 and 72 are duplicates.
Q Okay.
A Number 93, number 104, number 115, number 118, number 122, number 129, number 135, number 137, number 147, number 148, number 186, number 190, number 198.
Q Okay.
A That's what I got up to.
Q Thank you.
A Oh, and I have a couple more.
Q Oh?
A Sorry. Number 259.
Q Uh-huh.
A Number 296, number 306.
Q Who chose the medical articles that are included, the three hundred and -- I guess, 335 medical articles that are included on your reliance list?
A Who chose all of them?
Q Uh-huh.
A I chose the majority of them. Some of them were provided to me by counsel, many of which I already knew about before starting this process. And the majority of them were identified using the literature

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search.
Q Did you perform the literature search for this case specifically?
MS. KABBASH: You mean Sacchetti or --
BY MS. FITZPATRICK:
Q No. The general reports that you issued.
A Yes. Although I frequently run literature reports to answer my own questions anyway.
Q Did you run, specifically, the literature search for documents for your Prolift report?
A Yes.
Q And did you run a literature search for your documents for your TVT-O report?
A Yes.
Q And you testified that you have added some documents. Why did you add documents to your reliance list between February and March?
A So some of the documents came about because I was reviewing plaintiff's reports and plaintiff's depositions, and they were citing articles that I was not familiar with so I wanted to read those. Some of them came about as part of my review of my general report and -- I'm sorry. As review of my -- the Sacchetti report.
And I realized that some of the statements

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that I was making in the Sacchetti report was not necessarily backed up by the medical literature in my Prolift or my TVT report. So that resulted in my doing a literature search regarding some of my opinions in the Sacchetti report.
Q And was that the endometriosis articles that we were discussing?
A Yes.
Q Anything else that you did an independent literature search of between February and March besides the endometriosis?
A Not that I can recall.
Q And the articles on endometriosis, I think you said there were five of them. Were those all of the articles that your literature search pulled up on those particular topics or just the ones that you're relying on in support of your opinions?
A These are just the ones that I took notes on, that I thought were the most substantial.
Q And do you remember what actual search you plugged in to get those articles? I assume you did a PubMed search for this?
A Yes, that's correct.
Q And do you remember what search terms you were using?

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A I was probably using "endometriosis" and "pelvic pain," "hysterectomy." Oftentimes, it brings up one or two articles, and then you can find -- once you read those articles, you can -- they often cite other articles that they are relying on and that resulted in some of the documents that I pulled.
Q And how long did it take you to do that PubMed search and to find and review the articles on endometriosis that you've added?
A If I had to guess, maybe four hours.
Q Did you write your Prolift report yourself?
A Yes.
Q Every word of it?
A Yes.
Q And did you write your TVT-O report yourself?
A Yes.
Q Do you keep drafts of any of your reports?
A Yes.
Q And where are those drafts housed?
A In my computer.
Q Did you receive feedback on your reports or drafts of your reports from Ethicon's lawyers?
A Yes. They had comments, some of which I incorporated to some extent, others which I did not.
Q Is it fair to say that they were involved in

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the drafting process of those reports?
A To some extent, yes.
Q Okay. Do you know Dr. Vincent Lucente?
A Yes. I -- he trained me on Prolift. I've seen him lecture, and I've seen him and talked to him at meetings.
Q When did he train you on Prolift?
A I can't remember the year. It was actually, I think that this came up in the last deposition, so I know that there was documentation on it, but I can't recall the exact year.
Q And how did Dr. Lucente train you on Prolift?
A I went to St. Luke's Hospital in Allentown. There was a didactic session and then a hands-on session where we were in the OR with him.
Q Have you spoken with Dr. Lucente at all about this litigation?
A No.
Q Have you ever discussed your Prolift report with Dr. Lucente?
A No.
Q Your TVT-O report with Dr. Lucente?
A No.
Q Any of the case-specific reports, have you discussed those with Dr. Lucente?

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A No.
Q Do you consider Dr. Lucente to be a colleague?
A How do you define "colleague"?
Q Well, I thought it was a fairly -- well, I can look up the dictionary definition. Someone that you work with.
A I don't work directly with him, no.
Q Does he work in the same field as you do?
A Yes.
Q Do you respect the research that he has done in the field of pelvic surgery, particularly with respect to the Prolift?
A We'd have to go by that detail by detail. I feel like that's a very broad question.
Q Are you familiar with the research that Dr. Lucente does?
A Yes. We -- I know that he was involved in the initial development of the product, but, again, the details of the study, we would have to look at directly.
Q And in the training sessions for the Prolift, Dr. Lucente discussed his research and his work on the Prolift, correct?
A He must have. I mean, I can't -- it was a long time ago, and I can't recall. And I'm sure that he presented data because that was part of what I reviewed

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for the ProfEd from Ethicon.
Q Okay. And you have some research and publications by Dr. Lucente on your materials-reviewed list, correct?
A Yeah, I'm sure.
Q Okay. Have you ever heard anywhere that there were questions about the validity of the data that Dr. Lucente reported in his studies?
MS. KABBASH: Objection.
A Can you be more specific?
BY MS. FITZPATRICK:
Q Yeah. Has anybody ever indicated to you that there have been any questions about the validity of the data reported by Dr. Lucente in any of his studies?
MS. KABBASH: Objection.
A I'm not familiar with that, but a lot of studies you can look at, and you can invalidate them for a number of different reasons depending upon how you look at them.
BY MS. FITZPATRICK:
Q Has anyone ever indicated to you that Ethicon questioned the validity of the data that Dr. Lucente used in some of his studies?
MS. KABBASH: Objection.
A Can you be specific?

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BY MS. FITZPATRICK:
Q I'm just asking if you've ever heard that. Either you have or you haven't.
A I mean, not off the top of my head, but...
Q And you don't remember seeing that in any of the Ethicon documents that the Ethicon lawyers gave you to review in this case?
A I reviewed a lot of Ethicon documents, so...
Q Do you remember seeing that in any of the Ethicon documents that they gave you to review in this case?
A Not off the top of my head, no.
Q Okay. And you've relied on some of the findings and publications by Dr. Lucente, particularly for your Prolift opinions, correct, as opposed to your TVT opinions?
A Not necessarily. So this is a list of all the things that I've reviewed. I haven't necessarily -- I mean, we can look at my report to see if I've cited Lucente in any of my statements or my opinions.
Q So let's figure this out then.
So this is a list -- this Exhibit B is a list of everything that you reviewed, correct?
A Correct.
Q And within your report itself -- let me pull

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that out. Hang on one second.
Within your reports and the Prolift and the TVT itself, you have cited specifically to some of the articles that are on your reliance list, correct?
A Correct.
Q So is it fair to say that the articles that you have footnoted are the ones that you primarily rely on for your opinions; whereas, the list of materials you reviewed is a broader list that includes lots of things that you reviewed but maybe don't primarily rely on for specific opinions that are contained in your expert report?
A Yeah, that's accurate.
Q Okay. How many TVT-Rs have you implanted?
A TVT-Rs?
Q Yeah.
A I mean, I'm estimating here again. If I had to guesstimate, I'd say somewhere between 30 to 40.
Q Total over the course of your career?
A Yeah.
Q Do you use the TVT EXACT?
A Yes.
Q And how many of those have you implanted?
A If I had to guess, probably around 10.
Q How many TVT-Os have you implanted?

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A Hundreds, a lot.
Q Is it safe to say that that's your preferred polypropylene midurethra sling to use, the obturator slings?
A I have no preferred sling in the sense of do I prefer TVT, retropubic, or EXACT versus TVT-O versus a mini-sling. There's risks and benefits of each procedure. So these are presented to the patients. And then, with the help of the patients, we decide what the ideal sling for that patient is. So I have no preferred sling per se.
Q How come you've implanted hundreds of TVT-Os but only 30 to 40 TVT-Rs?
A But many of my patients don't want to have the risk of potential bladder injury, and they don't want to potentially have a catheter for a few days after the surgery. So they have in the past opted for the transobturator approach.
Q Is that the one you generally recommend?
A Again, I don't generally recommend anything. There are options, and we discuss the options. And what I -- you're also leaving out the many mini-slings that I do since the mini-slings have accrued more data. So I don't want -- I don't want to lead you down the wrong path.

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Q So let me get to that.
So you don't recommend it, but the majority of your patients choose the obturator procedure over the retropubic procedure; is that correct?
A Can we back up a little bit just so that we -- again, I don't want to go down the wrong path.
Q Sure.
A So the way I present this to patients, is there are three slings that we can choose from: a retropubic sling, an obturator sling, or a mini-sling. And over the last several years, many more patients have been opting for the mini-sling.
So if we had to break down the numbers over the last -- so, there's been an evolution, okay, of -- of our numbers in terms of which slings are we doing more commonly.
Q Okay.
A Not necessarily which slings is the preferred method by me. That's -- I can't answer that question. That's not what drives me to do surgery on patients. We have to make a decision collaboratively what the patient would opt for.
Q Okay. Well, let me then start with a more basic question just to get the record clear.
You agree with me that there are three types

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of polypropylene midurethral slings that can be used to surgically correct stress urinary incontinence, correct?
A Well, it depends --
MS. KABBASH: Objection.
A -- on how you label them, okay. There are obturator slings, there are retropubic slings, and there are mini-slings, and there are different approaches for each of them in terms of the technique.
BY MS. FITZPATRICK:
Q Okay.
A Okay.
Q But let's start with just -- I want to make sure I've got the general bucket.
It is within the standard of care to use a retropubic midurethral sling for the treatment of stress urinary incontinence, correct?
A Correct.
Q And it's within the standard of care to use the obturator sling, midurethral sling, as a surgical intervention for stress urinary incontinence, correct?
A Correct.
Q And it's within the standard of care to use a mini-sling for the treatment of stress urinary incontinence, surgical correction of stress urinary incontinence, correct?

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A Correct.
Q And in addition to those polypropylene slings, it's also within the standard of care to use autologous fascial sling to treat stress urinary incontinence, correct?
A That's correct.
Q And do you offer that procedure to your patients?
A It's discussed. It's often not -- rarely, if ever, selected.
Q Okay. And it's also within the standard of care to use a Burch procedure for surgical intervention for treatment of stress urinary incontinence, correct?
A Sure.
Q All right. And do you offer Burch procedure to your patients?
A No.
Q So that's not offered. So if a patient is coming in to see you for the treatment of stress urinary incontinence, the four options that you would discuss with that patient are the retropubic sling, the obturator sling, the mini-sling, and the autologous fascial sling, correct?
A Yes, that is true. However, much more time is spent discussing the midurethral sling because that is,

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by far, in my opinion, the -- has the best outcomes with the least complication rates.
Q Okay. And we'll get to that, but at least those are the four options that are discussed that one of your patients has available to them?
A That's correct.
Q Okay. And your preference as a physician is to use one of the polypropylene slings as opposed to the autologous fascial sling?
A Yes. Unless a patient comes here saying I don't want mesh, so mesh is off the table.
Q Okay. And so you'll agree with me that there's a risk -- different risks, risk/benefit profile associated with each of those four surgical interventions, correct?
A That's correct.
Q And so there are risks and benefits to the retropubic sling that are different than the risks and benefits associated with the obturator sling, correct?
A Correct.
Q And the risks and benefits of the mini-sling are then different still?
A Correct.
Q And the risks and benefits of the autologous fascial sling are different again?

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A Correct.
Q And so when a patient comes in and is looking for a surgical intervention for stress urinary incontinence, your job as a physician is to discuss each of these four surgical options with that patient, correct?
A Correct.
Q And your job as a physician is to present all of the information on the different risk/benefit profiles for each of these particular procedures, correct?
A Correct.
Q And then it's up to the patient to decide which profile best suits her, correct?
A Yes and no. It's collaborative. So there's information that we sometimes incorporate from urodynamic data. There's information from physical examination. So it's not simply about patient preference; although, that is one component of the decision-making process.
Q All else being equal though, you don't recommend one particular type of sling over the other, do you?
A So, for example, when you say "all else being equal" -- I'll give you an example. So what I call

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the -- okay.
So, for a typical patient that would come in as being a good candidate for a midurethral sling, okay, someone has hypermobility, someone that is young, someone that does not have atrophic epithelium, this is somebody that, in my opinion, is very likely to do well with any midurethral sling, okay, in terms of efficacy.
Q Okay.
A So then it comes down to -- and also adding to that, someone whose urodynamic profile also fits this. So then it comes down to, okay. We've got three sling options for you. We've got one that has the longest term data, but you run the risk of having a bladder injury.
Okay. We've got one that also has long-term data, but not as much long-term data. We can avoid the risk of a bladder injury, but we are operating through the groin. So there is a potential to have leg pain for 24 to 48 hours after the procedure. And you will have little incisions in the groin.
Or we have a third procedure that does not have as much long-term data as the other two, but we can avoid the bladder and avoid going through the groin, thereby minimizing the postoperative leg pain.
Q And what you just ran through, is that kind of

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in a nutshell what you would tell your patients who are looking for surgical intervention for stress urinary incontinence?
A Only those patients that can be -- or that would have good outcomes with any of those three slings.
Q And do you tell any of your patients about the potential for chronic pain?
A Yes.
Q And what do you tell them about chronic pain associated with retropubic?
A I tell them, as with all surgery, chronic pain can be something that can happen. And in this case, in rare circumstances, it can be chronic pelvic pain and it can be dyspareunia in a small subset of patients.
Q And what do you tell your TVT-O patients about the potential for chronic pain?
A That's across the board for all three of them.
Q Do you tell your TVT-O patients that there's an increased incidence of chronic leg or groin pain for TVT-O patients over retropubic patients?
A Yes. Although I do say that the chronic pain is very low and, over time, dissipates.
Q And what do you tell your mini-sling patients about the potential for chronic pain?
A Again, with all -- this is a conversation

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that, for chronic pain, that I have with any patient that I'm operating on.
Q So you don't differentiate chronic pain between the retropubic and the TVT-O and the mini-sling procedures?
A No.
Q Okay.
A Just for all three of them, chronic pain is very unusual.
Q Is that in your experience or do you believe that's supported by the literature?
A Both.
Q In what's reported in the literature comes in -- well, you'll agree with me that there's no literature that has primarily looked at safety as an end point for any of these devices, correct?
MS. KABBASH: Objection.
A Actually, that's not true. I just read an article that did -- you know, I always wondered about this because I would assume that there were very few articles that did look at safety as an endpoint for a number of different reasons, but I did come across an article in my review recently, that did look at safety and complications as an endpoint, as a primary endpoint.
BY MS. FITZPATRICK:

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Q What was that?
A Do you want me to look it up?
Q Yes, that would be great.
A Let's see if I can do it. I would have to pull the article to look at it.
THE WITNESS: Do you have our list? Do we have articles here that --
MS. KABBASH: Would you be able to identify the article, what it is?
THE WITNESS: Can you pull Zhang, Z-H-A-N-G.
MS. KABBASH: If you want, we can do that at the break.
MS. FITZPATRICK: Yeah. Why don't we do that at a break.
THE WITNESS: Okay. Do you want me to look for this now or we'll do it on break?
BY MS. FITZPATRICK:
Q So you've identified as Zhang, which I think is on your third page under TVT-O, correct?
A Right. But, again, I'm not sure. I have to look at the article because I didn't notate it. And I'm just trying to go off memory here.
Q Why don't we pull that at a break.
But was it your recollection that that was a randomized control trial?

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A Yes.
Q Okay. And it looks like here that there were 140 patients involved?
A Correct.
Q And do you believe a randomized control trial with 140 patients enrolled is sufficiently powered to look at safety data as a valid endpoint?
A Well, it depends on what you have to compare it to, right. We're doing a literature search to answer our questions. We have to do the best that we can.
I would love to have a randomized control trial with 3,000 patients, but that doesn't exist, at least in this particular case.
Q But do you believe that 140 patients is adequately powered to look at safety as an endpoint for the TVT-O device?
A I think it can be. If it's all we have, it's what we have to go on. It is a randomized control trial which has benefits in and of itself. There are other ways to look at safety besides randomized control trials, but we consider the randomized control trials to be one of the gold standards.
Q So you believe that the Zhang article -- and we can pull a copy of that at a break -- is a randomized control trial that has safety as an endpoint?

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A I'm not sure. I don't want to say that. I'm not going to pontificate about that until I see the article.
Q Let's pull the article and we'll come back to that. I don't want you to have to guess as to what it says.
Let me go back to just some basic questions before we get into all this. How many Prolifts have you implanted?
A Hundreds.
Q And do you use the Prolift+M?
A Well, I don't use Prolift+M anymore, but I did at one point when it was available.
Q Did you switch from the traditional Prolift or Prolift+M when it was available?
A Yes.
Q Why'd you switch?
A The idea of it sounded better to me, theoretically. I didn't see the harm in switching. I only saw a potential benefit in switching; although, my outcomes weren't particularly dissimilar between the two.
Q And what were the potential benefits that you saw when you switched?
A Less polypropylene and more absorbable material.

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Q And you'll agree with me that, at least in theory, the least amount of the foreign body, the polypropylene that you leave behind in a woman's pelvis, the better the outcome for the woman?
A Not necessarily.
Q In what circumstance do you think that more polypropylene is a better option for women?
A Well, you don't want to leave one strip of polypropylene because then it won't be as supportive. So you need the minimum amount to be supportive.
Q Fair enough. But you agree with me that you want to use the minimum amount of polypropylene necessary to effectuate a repair?
A A good outcome, yes, both with safety and with efficacy.
Q And how many Prolift+M's did you implant?
A Okay. So when you asked me how many Prolifts, I was including +M in that. So I really can't make the discrimination between the original Prolift and the Prolift+M because I'm not sure when my hospital switched to the +M.
Q Did you make the decision to switch or did your institution make the decision to switch?
A I think it happened automatically, and when I

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checked on it, I was happy that it happened.
Q Okay. How many TVT ABBREVOs have you implanted?
A One.
Q Well, I think we talked about the EXACT. How many TVT SECURs have you implanted?
A One.
Q What mini-sling do you use?
A MiniArc.
Q Why do you use the MiniArc?
A It has the same weave as the Gynecare products. It felt very similar on a clinical basis to the Gynecare product that I previously used. And the transient postoperative leg pain is virtually eliminated with it. The outcomes are about the same as the longer slings.
Q Do you believe the mini-slings have the same efficacy in curing stress urinary incontinence as the obturator slings?
A We don't have long-term data on that, but the data that we do have on it appears to be similar so far.
Q Okay. And do you believe that the mini-sling is as efficacious as a retropubic sling?
A Again, it's the same answer. So in the midterm, the five-year data, it looks about the same,

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but we don't have the long-term data that we have with the retropubic slings.
Q Why did you implant only one TVT SECUR?
A I didn't like the delivery method.
Q Okay. And what didn't you like about the delivery method?
A I thought there was a blade used to implant it. I felt like it was wider than it -- wider than I would have liked it to have been. I liked the idea behind a mini-sling so I tried it, but there was some blood loss when I used it, and I just preferred -- if I was going to do that at that time, it was going to be TVT-O. And then the MiniArc came out and that seemed to be a better option for a mini-sling.
Q And why did you only implant one TVT EXACT?
MS. KABBASH: You mean ABBREVO?
A TVT ABBREVO.
BY MS. FITZPATRICK:
Q Oh, sorry. ABBREVO, yes.
A You know, at the time, I didn't -- I hadn't seen any data on the TVT ABBREVO. It just so happens that it was in the operating room, and I think that they had run out of TVT-Os. So the next best option was a TVT ABBREVO. So we used the TVT ABBREVO, but I never stuck with it because I felt like I'm still going

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through the transobturator and I would rather use what I had longer-term data on, if I'm going to go through the transobturator canal.
Q And I think you told me before, but I can't remember, that you've done about 10 explants, is that right, 10 to 20?
A Yeah, that's about right.
Q And what products have you removed -- well, let me ask you this: How many of those were pelvic organ prolapse products?
A Now I'm really guessing. So I would have to say a little more than half would be pelvic organ prolapse products, polypropylene.
Q So maybe like a 60/40; does that sound about right?
A If I had to guess, sure.
Q Now, when you said that you had had a couple of patients that you shared with Dr. Blaivas, was he performing mesh-removal surgery on those patients?
A So the first patient that I recall was a patient with prolapse not related to mesh, but she had a very complicated condition where she had a fistula as a result of having chronic prolapse. So her bladder fistulized into the vagina and she was just leaking urine. She was an elderly patient, and she was very

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uncomfortable with what -- with her -- with everything that was going on. Her bladder was kind of eroding out through the opening. Somewhat of a disastrous outcome from just managing prolapse with observation.
But anyway, this was a patient that was very complicated and so, therefore, I sent her to somebody with a little more gray hair, which is Dr. Blaivas.
Q He does have a little more gray hair than you.
A Yeah.
Q Have you ever sent any patients to him for mesh-removal surgery?
A There was a mutual patient that we had, and I'm not sure if he removed the mesh or I removed the mesh. And she may have been going to him for an autologous fascial sling after I removed a sling. That might be the case. I don't recall sending anybody to him for removal of mesh.
Q Okay. So if a woman comes to you and needs mesh removal, are you the one who performs that surgery or do you refer those out to other physicians?
A I mean, it depends. You know, most cases that I believe -- there have been patients that have come to me that have been fine and they wanted their mesh removed for no reason. So I won't do that. If you want your mesh removed, you have to go elsewhere, especially

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if there's nothing wrong. Everything is going well. You're happy. You just want the mesh removed because you're nervous about the commercials you're seeing on TV. So that is one circumstance where I would refer.
If a patient had a symptomatic exposure, for example, that's something that I can very easily manage.
Q Have you referred patients to other physicians for mesh removal associated with symptom complications?
A I may have sent patients for second opinions, just complicated patients that may need second opinions to make sure that we're doing the right thing, but...
Q Okay.
MS. KABBASH: Fidelma, can we plan on a break?
MS. FITZPATRICK: Yes. I was just going to suggest that.
(Whereupon, a brief recess is taken.)
BY MS. FITZPATRICK:
Q Now, in your experience in removing mesh products, have you been able to remove all of the mesh from the patient?
A I don't necessarily need to. For most of the indications, it was simple exposure.
Q And would you agree with me that particularly with the obturator sling, it's not possible, absent very extensive dissection, to remove a sling from the

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obturator space?
MS. KABBASH: Objection.
A Okay. It might be difficult to do. However, I think it's rarely necessary to do, if ever.
BY MS. FITZPATRICK:
Q But putting aside the necessity of it, if for some reason a woman should have that mesh removed, that's an extremely difficult and extensive surgery, correct?
A Difficult, but not impossible.
Q And are you aware of any other surgeries, besides the placement of the transobturator sling, where surgeons utilized the transobturator space?
A Well, for pelvic --
Q Anything.
A For pelvic floor repair. We're frequently in that space when we do a prostatectomy, and when you're doing a node section, where there are nodes in the obturator space. So we're not infrequently in that area, and we frequently dissect right over the obturator nerve. Although, I don't do those surgeries anymore. I did in training.
Q So it's testimony that surgeons are not infrequently in the obturator space for surgical procedure?

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A Transabdominally or robotically.
Q And that's a different approach than is used with either the Prolift or the TVT-O, correct?
A Correct. But it's not an unfamiliar space.
Q Do you know of any other product that is permanently implanted into the obturator space?
A No.
Q What surgical --
A Well, I'm sorry. To go back on that, there are people who leave nonabsorbable sutures in that space as part of their pelvic organ prolapse repair.
Q And well, let's -- I'm going to actually get to procedures to treat pelvic organ prolapse.
What surgical procedures do you currently use to treat pelvic organ prolapse?
A Native tissue repairs.
Q Uh-huh.
A Transvaginal repairs with mesh augmentation.
Q Uh-huh.
A Robotic sacrocolpopexy that I do with a robotic surgeon.
Q Uh-huh.
A That's it.
Q And I think we talked about the product that you use for the mesh repair is the Elevate; is that

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right?
A That's correct.
Q Do you use any other product?
A I used to use Prolift but not anymore, obviously.
Q And with the robotic sacrocolpopexy, do you use mesh?
A It's called Y-Mesh. It's an AMS product.
Q And that's an AMS product that you use for -- and are those abdominally done; is that correct?
A Yes.
Q And do you use anterior colporrhaphies?
A I would consider that as part of the native tissue repair.
Q If the Prolift was still on the market, would you continue to use it?
A Yes.
Q Would you continue to use it in absence of the 522 studies and data that the FDA requested on Prolift?
A Well, that's a very hypothetical question. So they -- they never did the 522 studies, correct? They just withdrew the -- the mesh. So if they hadn't done the 522s, would I be using it? Yes, I probably would as I am with Elevate.
Q But you know that there's 522 studies underway

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for Elevate, correct?
A Correct, but if Prolift were still on the market, they would have been underway for Prolift if they decided to put the money into it, so...
Q Do you think that Ethicon should have performed clinical trials, as required by the FDA, to establish the safety and efficacy of the Prolift and, therefore, keep it on the market for women today?
MS. KABBASH: Objection.
A As far as I know, that was a company decision based on a financial decision, not on a safety and efficacy decision. If you asked me personally, do I wish that Prolift was still on the market, the answer was yes, but...
BY MS. FITZPATRICK:
Q Do you wish Ethicon had done those studies so Prolift was still on the market?
MS. KABBASH: Objection.
A Yes.
BY MS. FITZPATRICK:
Q Do you think that Ethicon's decision to withdraw the Prolift from the market instead of doing the clinical studies did a disservice to women?
MS. KABBASH: Objection.
A It didn't do a disservice. There are other

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products that can be used. So its coming off the market, it did not result in a major hole in the ability to treat patients. It just -- we can still do transvaginal procedures in a similar way, fashioning things like we did with Prolift.
BY MS. FITZPATRICK:
Q What do you mean by that?
A So, for example, we were able to use a total Prolift, which was one piece of mesh that was placed in patients who had either concomitant hysterectomy or previous hysterectomy. There is no product that is like that that is available now.
So if you wanted one piece of mesh to wrap around the apex of the vagina, you have to fashion it out of either an anterior -- right now, an anterior or posterior Elevate. You have to sew it together so that you don't have a gap between the two pieces of mesh.
So even though that product doesn't exist anymore, we can make something similar to it, albeit a different delivery system, but in terms of the anatomy of the mesh.
Q And it's with a different manufacturer, right?
A Correct.
Q Now, when you're doing a surgical intervention for the treatment of POP, do you take the POP -- you

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consider the POP-Q score of the patient, correct?
A I don't use POP-Q. I use the Baden-Walker System. It's easier to explain to the patient.
Q How do you explain that to a patient?
A So I tell them that we scale prolapse on a scale of up to four, and I go through the scaling of it. And I tell them what they are. And I tell them, patients are usually not symptomatic until they're a three, until the bulge is at the enteritis or just at the enteritis. And that some patients are referred with grade 2 prolapse even though they're asymptomatic. So it's helpful to say, Yes. You do have grade 2 prolapse, but so does everybody else walking around out there that's had a couple of vagina deliveries. It doesn't mean we have to do anything about it.
Q Which leads me to my next question.
You have to take into account the clinical symptoms of the patient before recommending a surgical intervention for pelvic organ prolapse, correct?
A Correct.
Q And it's important to consider how the pelvic organ prolapse is affecting the patient's quality of life, correct?
A Yes.
Q And so when you're looking at evaluating the

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outcomes of your pelvic organ prolapse repair surgery, do you agree with me that the functional outcomes are the most important measure of success?
A What do you mean "the function outcomes"?
Q The clinical symptoms, the resolution of clinical symptoms for women.
A I think that's very important.
Q And you agree with me that there are certain women who can still have some degree of prolapse, but the surgery controls or corrects the clinical symptoms that she was having and that would be a successful surgery, correct?
A At that moment in time. However, there's no way to predict whether an anatomic outcome that was suboptimal, could ultimately result in a clinical suboptimal outcome.
Q And there's also no way to predict that a woman coming out of surgery who had what would appear to be a better anatomic outcome, there's no way to predict what her clinical symptoms or clinical problems are going be later in life, correct?
MS. KABBASH: Objection.
A We don't -- I don't believe we have any data to support that.
BY MS. FITZPATRICK:

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Q And you agree with me, obviously, that the native tissue repairs and the colporrhaphies that we discussed are within the standard of care for treatment for pelvic organ prolapse?
A Yes.
Q And I think we discussed an anterior colporrhaphy. Do you offer native tissue repairs in the posterior compartment as well?
A Yes.
Q And do you offer native tissue repairs in the apical compartment as well?
A Yes.
Q And what percentage of the surgeries that you do currently for POP would be the native tissue repairs?
A I would say around 40 percent.
Q Okay. And what percentage of the surgeries that you do for pelvic organ prolapse, would be the vaginal placement of the Elevate system?
A I would say about 50 percent.
Q And what percentage of the pelvic organ prolapse surgeries that you do are done with the robotic sacrocolpopexy?
A The remainder 10 percent.
Q So I'm going to ask you the same series of questions that I asked you about the slings. Each of

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these surgical interventions has a different risk/benefit profile, correct?
A Correct.
Q And when you sit down with a patient, it's your job to tell her the potential risks and benefits of each of these separate surgeries, correct?
A Correct.
Q And to maybe make recommendations, what might be best in her personal circumstance, but allow her to make her own decision about which risks and benefits she is willing to accept, correct?
A Correct.
Q Now, you've worked as a preceptor for Ethicon, correct?
A Yes.
Q And that goes back to about 2003, correct?
MS. KABBASH: Objection.
A I'm not sure.
BY MS. FITZPATRICK:
Q What's your recollection of when you started to work with Ethicon as a preceptor?
A I think it was after that. I don't think it was quite that early, but, again, I don't recall.
Q Since they didn't come in the handy little folders they were supposed to come in, it just came in a

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stack, it might take me a little bit longer to find this stuff than I wanted it to.
MS. FITZPATRICK: Can we mark this as an exhibit?
(Exhibit Fromer 9, Document dated 3/29/2012, re: Master Consulting Agreement, marked for identification.)
BY MS. FITZPATRICK:
Q Let me show you what's been marked as Exhibit 9. Do you recognize the document that I've just handed you?
A This looks like a contract.
Q And it's a contract between you and Ethicon, correct?
A Correct.
Q And do you recall when you entered into that contract?
A I don't recall it, but it says here that the agreement shall commence on March 29th, 2012.
Q And you recall, though, that you worked for Ethicon long before 2012 and before you became an expert witness in litigation, correct?
MS. KABBASH: Objection.
A I don't think I ever worked for Ethicon. I wouldn't say that. I think in my whole life, I haven't

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made more than a few thousand dollars from Ethicon.
BY MS. FITZPATRICK:
Q Well, would you consider preceptoring for Ethicon to be working for Ethicon?
A Again, this is not -- you phrased it initially as I work for Ethicon. I don't work for Ethicon. I was hired by Ethicon, in my recollection, to run a training lab for them and participate in training other surgeons on how to use the products.
Q And you have been hired by Ethicon to do that in connection with the TVT device, correct?
A It could have been one of a few of the devices. I don't recall.
Q And you recall that you did preceptoring for the TVT-O device, too, correct?
A I think so. It might have been TVT EXACT. I don't know if it was the original retropubic or the TVT EXACT.
Q But you recall that it was either the TVT-O or the TVT EXACT?
A Correct, or TVT-O.
Q Well, and you preceptored for the TVT-O, correct?
A Yes, possibly.
Q And you've also preceptored for the Prolift,

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correct?
A Yes.
Q And you've also attended cadaver labs sponsored by Ethicon, correct?
A I have preceptored. Are you talking about teaching or attending?
Q You both attended one and got trained at one, and you taught them, correct?
A Okay. I don't -- I don't remember the training lab, but it's very possible that I did one.
Q Okay. And did you ever get trained by Ethicon on TVT-S?
A I don't remember.
Q Okay. You don't remember.
A Do you mean in a cadaver lab, a formal training in a cadaver lab?
Q Yes.
A I may have. I mean, I may have used it in one of the cadaver labs. I don't recall.
Q And you've also attended educational dinners that were sponsored by Ethicon over the years, correct?
MS. KABBASH: Objection.
A Educational dinners? For example, what do you mean?
BY MS. FITZPATRICK:

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Q Dinners that were sponsored by Ethicon concerning their products.
A I do remember a dinner that was sponsored by Ethicon. However, it was more of a roundtable discussion for OB/GYNs that -- where there was no formal teaching about their products. It was more a conversation about incontinence and prolapse and broad discussion.
Q And you've also arranged with Ethicon to sponsor a women's health seminar at Hackensack University; do you recall that?
A Well, we've done a few seminars for patient outreach for a variety of different female urology issues. We had one that was sponsored by AMS. We may have had one that was sponsored by Gynecare. I don't know if it ever got off the ground because it might have been -- it might have -- I remember there being multiple ones that were going on simultaneously from -- that were sponsored by different companies.
Q Okay. But you do recall Ethicon being there, correct?
A No. I don't actually recall the Ethicon outreach program actually happening. I recall an AMS outreach program to women actually happening, but I don't recall the Ethicon.

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Q And do you recall conducting a cadaver lab with Dr. Vincent Lucente in 2012?
A No, he was not there. Vincent Lucente was not there, but we did have a cadaver lab. I don't think he was one of the people proctoring it.
Q You don't think he was there or you know that he wasn't there?
A He wasn't there.
Q And if documents suggested otherwise, those documents would be incorrect?
A That's correct.
Q Now, is this the only contract that you've entered into with Ethicon, the one that's dated March 29th, 2012?
A I don't remember.
Q In preparation for your deposition today, did you go back and look for any agreements or contracts that you had with Ethicon?
A No. But I did -- I did see this document at the TVT -- at my previous TVT deposition, I think I saw this document.
Q But you don't recall whether you have any other contracts with Ethicon or Ethicon has paid you for any other services beyond or after the date of this contract; is that right?

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A It may have happened, but I don't -- I just don't recall it.
Q Now, you know that the FDA has recently sought to reclassify the trocars that are used in the TVT-O/TVT-R procedures as class 2 medical devices?
MS. KABBASH: Objection.
A I do recall a recent reclassification by the FDA.
BY MS. FITZPATRICK:
Q And what was your understanding of that reclassification?
A That it was -- I don't really understand the significance of the reclassification. It certainly hasn't affected the use of my product, but I do know that it was reclassified.
MS. FITZPATRICK: So let's go ahead and mark this as Exhibit 10 and this is Exhibit 11.
(Exhibit Fromer 10, Reclassification of Urogynecological Surgical Mesh Instruction FDA Executive Summary dated February 26, 2016, marked for identification.)
(Exhibit Fromer 11, Reclassification of Urogynecological Surgical Mesh Instrumentation dated February 26, 2016, marked for identification.)
THE WITNESS: This one is the short one?

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MS. FITZPATRICK: Yes, the abbreviated version.
BY MS. FITZPATRICK:
Q Now, have you seen this before?
A No.
Q And so, if you look at page 5 of the abbreviated investigation.
A So pages 1 through 4 are not here.
Q It's in the larger version, if you want to take a look at pages 1 through 4.
A I don't like to see things out of context.
Q Sure.
A Do you want me to go to something or do you want me to read this document?
Q Sure. Why don't you start with page 4.
A Okay.
Q And in page 4, it indicates that the FDA believes that intraoperative and perioperative adverse events such as organ injury, perforation, and hemorrhage, and bleeding, and nerve injury and pain can be reasonably attributed to the urogynecological surgical mesh instrumentation and not the surgical mesh.
Now, is it your understanding that the urogynecological surgical mesh instrumentation are the trocars; is that correct?

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A I suppose it could be the trocars. It could be the Capios. There's a picture of a Capio here, so...
Q Yup, you're correct, but in the -- in the --
A I assume, yeah, I assume it's the delivery system.
Q Right, but the Ethicon products don't use a Capio, correct?
A That's true.
Q And it uses, instead, the trocar-based system, correct?
A Yeah.
Q Okay. And the trocar for the TVT-R is different than the trocar that's used for the TVT-O?
A Correct.
Q And if you turn to page 5 -- well, let me ask you this: Do you agree with the FDA that intraoperative and perioperative adverse events such as organ injury and perforation, hemorrhage and bleeding, and nerve injury and pain can be reasonably attributed to the urogynecological surgical mesh instrumentation and not surgical mesh?
A Yes. Although, I think those risks are rare in the case of TVT and TVT-O and Prolift.
Q Okay. And if you turn to page 5, you'll see that the FDA did a literature search of all MDRs

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reported from January 1st, 2008, to December 22nd, 2015, to find those associated specifically with the surgical mesh instrumentation; do you see that?
A The first paragraph?
Q It's in the second paragraph, the FDA searched all MDRs.
MS. KABBASH: I see that language in the first paragraph. You mean the first one under A?
THE WITNESS: I'm reading from each year.
MS. FITZPATRICK: No, second paragraph. The FDA searched all MDRs.
MS. KABBASH: Okay.
A Okay.
BY MS. FITZPATRICK:
Q And according to this report, the FDA identified a total of 463 MDRs using the search methods that they described above.
A Between 2008 and 2015?
Q That's correct.
A In the absence of knowing what the denominator is?
Q Uh-huh.
A Okay.
Q And that actually leads me to something.
You can't solely use the MAUDE database to

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determine what the incidence of adverse events from a particular product are, correct?
A Yes.
Q And one of the reasons is because you don't know what the denominator is, correct?
A That's correct.
Q And the other reason is because there's oftentimes underreporting of those adverse events to the FDA, correct?
A That's true. And sometimes the adverse events are not necessarily related to what -- whoever's reporting it is related to.
Q So you believe that looking at published literature is required as well?
A Correct.
Q Now, if you take a look at page 6 to 7, there's a chart that has manufacturer and brand name; do you see that?
A The one on top? The one on the bottom, okay.
Q The one on the bottom, that's right.
And so Boston Scientific Corporation had 316 MDRs associated, correct?
A Okay.
Q Do you see that?
A Yes.

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Q And are you familiar with the Pinnacle Pelvic Floor Repair Kit and the Uphold Vaginal Support System?
A I know them, yes.
Q And those don't use trocars; those use a Capio, correct?
A I mean, I see these -- I don't really -- I don't know that I would call -- make a differentiation between that. I mean, the Capio is a device that implants sutures, and you use it -- it's a long tool to get to where your fingers can't get to, which is the same thing that a trocar is. So if you're talking about definitions of trocar versus a Capio -- what is -- what is the question?
Q Do you think that the -- well, let's go back to the phrase. The urogynecological surgical mesh instrumentation use of the Pinnacle and Uphold vaginal support systems are the same as the urogynecological surgical mesh instrumentation that's used to implant the Ethicon devices?
A They are all different.
Q Okay. And Ethicon doesn't use a Capio, correct?
A That's correct.
Q All right. And Boston Scientific does?
A That's correct.

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Q So if you turn to the next page --
A Although, just to -- you know, you're talking about Pinnacle and Uphold. Those are pelvic floor repair kits, right?
Q Uh-huh.
A Whereas, TVT-O and retropubic TVT, those are stress incontinence procedures.
Q Okay. And what's used for the Prolift?
A So the Prolift is a delivery system.
Q What type of delivery system is used?
A It's a trocar.
Q So we can agree that the pelvic floor or the pelvic organ prolapse kits that are made by Ethicon use a trocar-based system as opposed to the Capio-based system that Boston Scientific --
A Correct.
Q So if you turn to the next page, you'll see Ethicon, correct?
A Uh-huh.
Q And you'll see that there are 65 MDRs for the Ethicon -- or the Gynecare TVT system, correct?
A Correct.
Q And there are 14 for the tension-free vaginal tape, correct?
A Well, I don't -- I'm not sure I understand the

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difference between the two of them.
Q And in fact, those two terms are often used interchangeably, correct?
A Yes.
Q So just looking at this, would you agree with me that the highest number of MDRs associated with a trocar system, as opposed to a Capio system, are associated with the use of the Ethicon products?
MS. KABBASH: Objection.
A I don't see the relevance of that.
BY MS. FITZPATRICK:
Q Okay. Well --
A And also --
Q -- we may disagree on --
A -- Prolift is not listed here -- listed here. I mean, we're comparing apples and oranges here.
Q Whether you agree with me or not, here's the basic question: Would you agree with me that the greatest number of MDRs associated with a trocar-based system are with the Ethicon products?
MS. KABBASH: Objection.
A Well, that may be true. However, odds are, the greatest number of products that were being used at the time were the Ethicon products, so...
Q And they caused the greatest number of MDRs

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that we know of here.
A That's probably as a result of the denominator.
MS. KABBASH: Give her half a second. Just a half a second.
I just want to state an objection to the last question.
MS. FITZPATRICK: Okay.
BY MS. FITZPATRICK:
Q You don't know what the denominator is?
A That's correct.
Q And nobody knows what the denominator is, correct?
A That's not published anywhere that we can find.
Q So when you say that Ethicon probably had the highest number because it has the highest denominator, you're guessing there? You have no data to support that guess, correct?
A That's probably true.
Q So the FDA also performed a literature review and it's in the -- I think it's the next -- okay.
So on page 30 -- starting at page 30 of that document, there's a discussion of the review of published literature conducted by the FDA. And if you

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look at page 31, it outlines the methods that were used; do you see that?
If you could read through that and tell me if you think that looks like a reasonable methodology to perform a literature review.
A Is this a literature review for --
Q That goes along with the reclassification, correct.
A For all prolapse and incontinence products?
Q Uh-huh.
A And only associated with devices, not native tissue repairs? This is only associated with devices --
Q Correct.
A -- correct?
And did they include randomized control trials where things were compared, where native tissue might have been compared?
Q I guess what I'm just asking you is about the methodology. Does that look reasonable to you?
A Yes. Assuming that they incorporated all the studies that are available to review that may -- may result in comparisons between devices and non-devices for the same procedure. It's hard to know whether or not those were included.
Q Is there any indication on this slide that

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those were excluded?
MS. KABBASH: Objection.
A Again, they don't specifically state whether it is or it isn't, so...
BY MS. FITZPATRICK:
Q Well, there's some limitations on the searchs that were done that are included in this method slide, correct?
A When you say "limitations," you mean the human subjects, written in English, published between 1967 and 2015?
Q Correct.
A Then there's exclusions.
Q Correct.
A But they only searched for devices, manufacturers. So hopefully, that would come up in their search, the randomized control trials that were done, correct.
Q So let's take a look at the next slide which is on page 32. So it had 207 references that were reviewed and 74 of those were related to the retropubic, correct?
A 207? Were there more?
Q Resulted in 207 at the bottom of page 31.
MS. KABBASH: Oh, I think you're on the wrong

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page.
THE WITNESS: Am I on the wrong page?
MS. KABBASH: Yes.
THE WITNESS: Oh.
BY MS. FITZPATRICK:
Q So there were 207 references that were reviewed?
A Okay.
Q And then the next slide on page 32 breaks down those references, those 207 references by procedure. And there were 74 of those that were retropubic, correct?
A Okay.
Q 64 which were transobturator and 32 that were mini-sling for the SUI?
A Correct.
Q For the pelvic organ prolapse, transvaginal repair was related to 33 references and the abdominal repair was by three, correct?
A Okay.
Q All right. So what I want you to do is to look at page 34 of this for me. And this shows the results of the literature search for organ perforation and injury; do you see that?
A Yes.

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Q And the retropubic number found a rate of 0.3 to 23.8 of those references.
A This includes bladder injury.
Q Uh-huh.
A Okay.
Q It includes organ perforation, organ injury, urethral injury, urethral injury twice, bladder injury, bladder perforation, rectal injury, cystostomy, and enterotomy; did I say that right?
A Enterotomy. Yes. Which is the same thing as bladder injury, an enterotomy. And they don't break it down according to the severity of the injury.
Q Correct.
A So certainly, you would agree that a bowel perforation would be much more of an issue than a bladder injury.
Q Sure. For purposes of -- since I don't have to agree with your questions today, we're doing it the opposite way. You do good at our job.
A Sorry. I mean, you're rubbing off on me.
Q 0.3 to 23 percent -- to 23.8 percent of organ perforation and injury, that's the rate, correct?
A Correct.
Q And you would agree with me that the studies that are going up to 23.8 percent of organ perforation

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and injury as defined here, that's not a rare complication, correct?
MS. KABBASH: Objection.
A Well, I mean, you'd have to break it down by injury. If you look specifically at bladder injury, it's -- you know, it can range between 15 and 20 -- probably up to 23 percent. And that's something that patients are counseled on with regard to any retropubic sling or any retropubic procedure regardless of whether they're using mesh, trocars or sutures.
Q So before I get to this next line of questioning, let me ask you this: It's important to know the frequency of a complication or how often it can be expected to occur, correct?
MS. KABBASH: Objection.
A Yes.
BY MS. FITZPATRICK:
Q And it's also important to know the severity of the complication, correct?
A That's correct.
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q And it's also important to understand the permanence of the complication, correct?
MS. KABBASH: Objection.

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A Correct.
BY MS. FITZPATRICK:
Q And you have to take all three of those, the frequency, the severity, and the permanence of the complication into consideration when you're counseling a patient on a potential risk of a product, correct?
A And also, the reality of the complication, right. So again, going back to my original discussion of a retropubic versus a transobturator sling, the patient goes in knowing there's a potential for a bladder organ injury during that procedure. And if they do not want to have a catheter because, in their eyes, a catheter is the worst thing in the world, even if it's just for three days, that's going to steer us away from a retropubic sling.
Q So I'm going to call that kind of the real-world consequences --
A Right.
Q -- correct? Okay. So let's put all four of those.
So it's important for a physician to counsel on the frequency, the severity, the permanence and kind of the real-world consequences of these decisions, correct?
MS. KABBASH: Objection.

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A Can you repeat the question?
BY MS. FITZPATRICK:
Q Sure. It's important for a physician to counsel the patient on the frequency of the complication, the severity of a complication, the permanence of a complication and this -- we'll call it the real-world implications of a complication?
A Yes, how a potential complication could affect their lives.
Q So the rate of a complication, as it's reflected here, is one of the measures and one of the things to counsel a patient on for a physician to be aware of, correct?
A That's true.
MS. KABBASH: Objection.
A Although, again, if you're specifically speaking about this rate of organ perforation up to 24 percent, I would not counsel a patient that you have up to a 24 percent chance of bowel injury.
BY MS. FITZPATRICK:
Q But we're looking at overall organ perforation injury the way that it's defined by the FDA here?
A That's fine, but that's not just reality, the way we talk to patients about it.
Q Fair enough. But this is the way that it's

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reported in the literature.
So here's what my point is --
A Actually, to correct you, it's not how it's reported in the literature. The literature usually pieces it apart because that is important.
Q Here's all I'm trying to get to: The transobturator, the rate is 0.2 to 5.8 percent, correct?
A Yes.
Q So there's a significantly lower rate of organ perforation and injury reported with the transobturator sling than the retropubic sling based on this literature review, correct?
A That is most likely because you're avoiding bladder injury.
Q And that is something that you would expect to see, a difference between the rates in the transobturator procedure and the retropubic procedure, because of the bladder injury that you've mentioned, correct?
A Correct.
Q All right. And with mini-sling, the rate is again lower. And is that something that you would expect to see and is consistent with your understanding, of the frequency of this organ perforation and injury as a class with a mini-sling?

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A Correct.
Q And for the pelvic organ prolapse procedures, there's a rate of organ perforation and injury between 0.7 to 13.1 percent, correct?
A That's what this says, yes.
Q Do you consider 13.1 percent to be a rare complication?
MS. KABBASH: Objection.
A I wouldn't call it rare. However, I would need to look at the study that shows 13.1 percent chance of organ perforation. That seems to be an outlier in terms of all the data that we have, and that I have accrued and written about in my report.
BY MS. FITZPATRICK:
Q But putting aside whether you agree with this statistic or what it's based on, 13.1 percent is not a rare complication?
MS. KABBASH: Objection.
A I would not call it rare.
BY MS. FITZPATRICK:
Q So if we turn the page then, to the vascular injury and bleeding. Now, this includes: hemorrhage, vascular injury, hematoma, and blood transfusion. So, again, these complications have been grouped under the heading: A vascular injury and bleeding.

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For the retropubic, the rate is 0.4 to 29.4 percent. And for the transobturator, it's 0.2 to 11.9 percent; do you see that?
A Yes, I see it.
Q And is that consistent with your experience in the difference between the retropubic and the transobturator with the risks associated with the retropubic and transobturator procedures?
A My experience is not within -- is not near this range of up to 29 or 11.9 percent, nor is that the experience that I've seen in reviewing the literature.
Q Okay.
A So again, I would say that these high numbers are outliers. And even though they presented it as a range, this is not reality or close to it.
Q Okay. So there's a range of a low to a high, correct?
A That's correct.
Q And is it your opinion that the reality of it lies somewhere in between?
A No. I think the reality of it is it relies on the very low side, and I have a lot of literature that can also support that.
Q So, when you're looking at this, you believe, although there's a range of 0.4 to 29.4 percent, it's

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more likely to be closer to the 0.4 percent?
A Again, they are stating this rate. I don't know -- you're not showing me the study that shows a rate of 29 percent vascular injury and bleeding, and I would be interested to see that study.
Q Okay.
A Same thing for the 12 percent transobturator and the 20 percent mini-sling.
MS. KABBASH: Can I just state and seek a standing objection because I understand why retropubic would be -- could be part of questioning, but a lot of the questioning that has happened in the past 20, 30 minutes has been very heavily on retropubic as specifically relating to surgical instrumentation and trocar use. And I'd just like to reiterate that Dr. Fromer is not being put up for a deposition on retropubic right now. Some of it may relate to her current opinions, but this is specifically on trocar use and surgical instrumentation, which I think is kind of outside the realm of what she's been put up for now. So I'll just state that standing objection.
BY MS. FITZPATRICK:
Q Okay. Would you agree that vascular injury and bleeding are more common with the retropubic over the transobturator sling?

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A I have to look at some of the data. There might be varying -- there might be varying results on that throughout the data.
In my personal experience, I don't see -- I -- the hundreds of cases I've done, I've transfused one patient and we've identified that she had a bleeding disorder after the surgery.
Q Okay. There's -- what's -- let me --
A The data also supports that.
Q Let me separate out.
There's your clinical experience in treating women, correct?
A Correct.
Q And you've implanted hundreds of women with some kind of polypropylene mesh for the treatment of stress urinary incontinence, correct?
A Correct.
Q And you've implanted hundreds of women with transvaginal mesh for the treatment of pelvic organ prolapse, correct?
A Correct.
Q But you haven't conducted any clinical studies on those women, correct?
A Not true. We reported on them in the Canadian Journal of Urology last year.

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Q How many?
A We can look at the numbers. I have to pull up the article. I don't know.
Q Can you tell me off the top of your head how many?
A Probably over a hundred. I don't remember.
Q So a fraction of them were reported, correct?
A That's true.
Q All right. And for the rest of those women, you don't follow them and you don't address their injuries in the same way that you -- or track their injuries in the same way that you did for the article that you published, correct?
MS. KABBASH: Objection. Lack of foundation.
A Not true. So, for example, blood transfusion, this is something that I do know because I have been tracking this. And there's only one patient that required a blood transfusion, and that was in the setting of a -- of a hemorrhagic disorder that she had.
BY MS. FITZPATRICK:
Q Where do you keep that data on your patients that I could take a look at?
A The one patient that I had, I can probably get her record.
MS. KABBASH: Objection. No, no, no, no.

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Hang on. I'm going to state an objection to the extent that you are seeking private patient information of Dr. Fromer. I don't know where you're going with this, but I'll just put it on the record.

MS. FITZPATRICK: Okay.

MS. KABBASH: And you're not going to volunteer any information about your patients that has not been reported in the medical literature.

You can speak generally about your experience, but we're certainly not going to disclose any private information of patients who have not filed lawsuits and waived their privileges.

BY MS. FITZPATRICK:

Q There's a group of patients that you followed for the article that you published in 2015, correct?

A That's correct.

Q And there was a methodology that you used for qualifying those patients for the study that you were doing, correct?

A Correct.

Q And there was a methodology that you used for tracking the outcomes for those patients, correct?

A Correct.

Q And there was a methodology that you used to do the statistical analysis to look at what the outcomes

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of those patients were, correct?

A Correct.

Q You don't do that for the rest of your patient population, correct?

A Correct, but I don't need to tell you how many transfusions in all the patients I've done have been.

Q I'm not focusing just on transfusions. I want to get an idea of what you do across the hundreds of women that you've implanted.

And so, apart from those who have been reported in the Canadian Urology Journal, you don't follow the methodology for selection for tracking and for statistical analysis across your clinical population, correct?

A Not in the past. However, this is not -- this is not a -- these are not long-term complications. This is an intraoperative complication. Are we just talking generally?

Q I'm just talking generally.

A Okay.

Q I want to understand what you have and what you don't have. And if you've done a statistical analysis of your clinical population in the same way that you did for the Canadian Urology Journal, I want to know what it is and how you did it. And if you didn't

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do it, then I know you didn't do it and I can move on. So that's what I'm trying to figure out here.

So, it's not in connection with your vascular injury or hemorrhage?

A I didn't do it.

Q So let me step back.

We've already discussed that there was a particular way that you undertook the methodology for the Canadian Urology Journal. You don't employ that same methodology for considering, including, tracking, and analyzing your clinical outcomes in your typical clinical patient who comes in, correct?

A That's correct.

Q That doesn't exist. So what does exist is the study that you did that was published?

A Correct.

Q And that's the only place that I could get the statistical analyses that would look at these different rates of complications across your clinical population?

A Correct.

Q Okay. And so then, in addition to that, there is the clinical literature. And you'll agree with me that the clinical literature is -- there's a significant amount of clinical literature that has reported on safety observations that were secondary to efficacy

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observations, correct?

A Safety observation -- I'm just repeating what you just said. Safety observations that were secondary?

Q Right. Secondary end point to the studies.

A They may have been the secondary end point, but that doesn't make the value of the information achieved from them any less.

Q I'm not suggesting that. I'm just asking you a simple question.

The literature that's out there safety -- apart from perhaps the Zhang study that we'll look at, safety is the secondary outcome and efficacy is the primary outcome of those studies. You'll agree with me on that, correct?

A Yes.

Q And then, in addition to those studies, there are metaanalyses that have been done that have looked at a collection of these studies and run their own statistical analyses to look at some of the rates of adverse events and complications that are associated with the various procedures, correct?

A That is correct.

Q All right. So all I'm trying to -- and slide 35, I'm just trying to ask you a simple question.

Is it consistent with your understanding that

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there's a higher rate of vascular injury and bleeding associated with the retropubic device than the transobturator device?
A Well, why don't we just look at one of the articles quickly that I've relied upon. I'm pulling out the Schimpf study.
Q Perfect. I'm going there. Great.
MS. FITZPATRICK: Can we mark this as the next one?
(Exhibit Fromer 12, Article titled Surgeon for Street Urinary Incontinence in Women: A systematic review and metaanalysis, marked for identification.)
A So I'm looking at the summary estimate of incidence.
BY MS. FITZPATRICK:
Q I'm sorry. What page are you on?
A I'm sorry. Page 1.E7.
Q Okay.
A It's table 3, rates of adverse events by sling type from randomized control trials and included adverse event studies.
Q Okay.
A So here you can see for TVT or for transobturator techniques, a .22 percent chance of blood loss greater than 200 cc's. And for retropubic, 1.5

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percent. If we move to transfusion, transobturator, 0.17 percent, retropubic 0.4 percent.
Q So based on Schimpf, it's your testimony that there is no difference between the vascular injury and bleeding associated with the retropubic transobturator and mini-sling?
A Well, there's a difference. As you said, it is slightly higher for the retropubic sling, but it's still less than one percent for a transfusion rate. Which I would not be telling a patient choosing between an obturator and a retropubic, you have a .17 percent chance with an obturator and a .4 percent chance with a retropubic. I'd be saying the chance is less than one percent.
All right. I'll start over again. Where did I leave off? Sorry. Okay. So --
MS. KABBASH: You said you would not tell a patient --
THE WITNESS: Right. I would not tell a patient that they have a .17 percent estimate of requiring a transfusion for a transobturator sling and a .4 percent chance of requiring a transfusion for a retropubic sling. I would say, in reality, the odds of your having a transfusion is less than one percent.
BY MS. FITZPATRICK:

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Q Okay. I feel like we're talking past each other because you don't want to talk about what I'm talking about, but we will move along.
MS. KABBASH: Objection.
A Just to clarify that, honestly, I pulled this article out because I wanted to make certain what I was telling you was my accurate opinion.
BY MS. FITZPATRICK:
Q Then maybe you can tell me your opinion because I've asked it two different ways, and you haven't agreed with either way. So let me figure out what's going on here.
Do you believe that there is a difference in the rates of vascular injury and bleeding between the retropubic and transobturator slings?
A There may be a slight increased risk with retropubic, but I think that they are both so low as to be insignificant -- an insignificant difference.
Q Do you believe that there's a difference in the vascular injury and bleeding between the transobturator and the mini-sling?
A My answer is the same. It's still less than one percent in most of the studies that we've looked at.
Q Okay. If you turn to the next page, nerve injury and pain. And keep Schimpf out, too, because

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this will be --
A Okay.
Q This includes nerve injury, nerve damage, leg pain, thigh pain, buttocks pain, and neurological symptoms, okay?
A Uh-huh.
Q Retropubic has a rate of 0.1 to 5.3 and transobturator has a rate of 0.8 to 30.8 percent. Do you believe that there's a significantly higher rate of nerve pain and injury associated with the transobturator sling over the retropubic sling?
A Did you say leg pain in your statement or did you say nerve damage?
Q Nerve pain, nerve injury, leg pain, thigh pain, buttocks pain, and neurological symptoms all defined at the top of that page for you.
A Sure. There's definitely a higher risk of transient leg pain with the transobturator sling than the retropubic sling.
Q Is there a greater rate of chronic leg pain associated with transobturator slings over retropubic?
A I think that this -- there may be a slight increase from transobturator to retropubic in chronic leg pain, but it is still a very low number.
Q And mini-slings, do you believe that there's a

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greater incidence of nerve injury and pain associated with the transobturator over the mini-sling?
A Again, the same answer. The transient leg pain is definitely an increased risk associated with the transobturator technique.
Q Now, taking a look at nerve injury and pain associated with the transvaginal repair, that's 6.0 to 39.1 percent as analyzed by the FDA using their literature review. Is that something that's consistent with your understanding of the incidence of nerve injury and pain associated with transvaginal mesh repairs using trocars?
A This doesn't say "transvaginal mesh repair." This just says "transvaginal repair."
Q But you realize that this whole thing deals with transvaginal mesh, correct? It's the placement of either --
A Okay.
Q It's the placement of either mesh or SUI or for pelvic organ prolapse.
A Okay. Because I was -- again, it goes back to the search and what they were including. But I understand you're telling me that these are all mesh, including the abdominal repair being a mesh sacrocolpopexy, correct?

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Q Right.
A Okay.
Q So all I'm asking you is: They report out 6.0 to 39.1 percent rate of nerve injury and pain associated with a transvaginal repair. Is that consistent with your understanding?
A Again, it's a very wild range that's listed here. And I'm sure if you look at certain studies, you can see higher rates than lower rates. But if you're looking at the global picture, the number is probably closer to the 6 and possibly lower than the 39.
Q Okay. And that's based on the literature that you have cited here, correct? That's the basis for your opinion on that?
A Yes.
Q 71.E9 of Schimpf or Exhibit 12. Groin pain, if you look about halfway down. Dr. Schimpf and her colleagues looked at the incidence of groin pain associated with the mini-sling, the retropubic sling, and the obturator sling, along with some other native tissue procedures or, I should say, the autologous fascial sling and the Burch procedure, correct?
A Correct.
Q And what Dr. Schimpf and her colleagues concluded was that the summary estimate of incidence of

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groin pain with the obturator was 6.5 percent over the retropubic of 1.5 percent, correct?
A Correct.
Q And that was both higher than the incidence with the mini-sling which is 0.62 percent, correct?
A Correct. Although, we would have to look into more detail about whether that 6.5 percent is transient or how long-term that is because that's important when you're looking at the complications.
Q But Dr. Schimpf, in this article, hasn't done that analysis, correct?
A No. Although, I have a list of some studies that looked at that.
Q Have you done a metaanalysis to assess the incidence of chronic groin pain with the obturator, retropubic, and mini-sling?
A No. I was referring to my list of -- other list of articles that look at this in terms of long-term, short-term.
Q But are those metaanalyses or are those individual --
A I'm not sure.
Q Either randomized control trials or prospective studies?
A I think it was a randomized control trial.

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Q And so one of the benefits of this type of metaanalysis done by Dr. Schimpf, is she was able to pull all of that stuff together, sort out the apples and oranges, and do a statistical analysis. And you haven't actually done that, correct?
A That's true.
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q So what she's reporting here is, and would you agree, that there's a significantly higher chance of groin pain with the obturator sling over either the retropubic or the mini-sling?
A Yes, that is correct.
Q And 6.5 percent is not rare, correct?
MS. KABBASH: Objection.
A I would call that 6.5 percent. Whether it's rare, uncommon, common, prevalent, I don't think there's any definition for that.
BY MS. FITZPATRICK:
Q Well, I'd like to know what the definition is because you've used the term "uncommon" or "rare" many times in your deposition today, in your opinions, concerning the incidence of certain adverse events associated with the polypropylene midurethral slings. And I'd like to know what you mean by "rare" and

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"uncommon" and at what point that stops.
A Okay. That's a good question.
When I'm talking to patients about this, which is, I think, relevant to this conversation because, at the end of the day, we're dealing with the women who are having these surgeries. I don't really use the word "rare." I use the numbers. Okay. So if I think something is less than one percent, like bleeding, transfusion, I will call it less than one percent. If something is less than 10 percent, I'll call it less than 10 percent. If we're talking about something like bladder injury, I'll tell a patient there's a 15 to 20 percent chance you may go home with a catheter today. And I don't use the words "common" or "uncommon" because, at least with patients, because it results in this kind of difficulty with understanding.
So when we talk about -- when I use that word, you can -- I can bring up the numbers for you that I have written down as reminders for myself.
Q But you were the one that was using the words, so I'm trying to understand what it was that you were telling me in the course of the deposition.
What do you tell patients is the chance of them leaving your operating room with groin pain following an obturator sling?

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A I prepare them for the fact that your legs are going to hurt after the surgery. It's probably going to last for 24 to 48 hours. You will get pain medication for that. And after that, it will dissipate and eventually go away.
Q You told me that the way you counsel patients, is you tell them less than one percent, less than ten percent. What do you tell them with the groin pain associated with the obturator sling?
A I tell them they're going to have pain afterwards. I just assume it's going to happen. I prepare them for that because I don't want them to be confused. That is something that happens. We're operating on the groin, the site of making an incision in the leg, so that's their site of pain.
Q What do you tell them is the potential for chronic groin or leg pain following the obturator procedure?
A Less than one percent.
Q And what is that based on?
A Studies that have been done in the literature as well as my own review of my patients.
Q Show me what you've got that's less than one percent for chronic.
A So Saradi 2013.

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Q Do you have a copy of that with you?
MS. KABBASH: I don't know if we do. We can look. Do you want to take a break?
MS. FITZPATRICK: If you've got it handy. I don't want to waste too much time, but if we're going to talk about certain studies that you have, I'd like to have them on something other than a thumb drive.
MS. KABBASH: Well, if you want us to look for Sorrotti, I can go look for Saradi.
MS. FITZPATRICK: Okay. That would be great.
BY MS. FITZPATRICK:
Q What other ones are you going to? Let's get them all at the same time.
A That's -- I mean, to be honest, that's the best one because it went out to five years.
Q And would you base what you tell your patients on a single study?
MS. KABBASH: Objection.
A Very few of these studies have looked at groin pain going out to five years, so that's why I've used this particular study.
BY MS. FITZPATRICK:
Q Is it the only one?
A No. There are other studies, and I'm sure we can find other rates of groin pain. There is the Zhang

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study that went out to a year and that was 3.8 percent, which is on the higher end.
Q Do you counsel your patients if there's a possibility of up to 3.8 percent chance of chronic pain, groin pain, and leg pain up to a year?
A I don't use that number. However, I will tell you that we do discuss that being a possibility, and we do have patients who are marathon runners, bodybuilders, who opt not who have a TVT-O for that reason because they don't want that even small chance of having that problem.
Q And is there anything else besides Saradi that you rely on, for your advice to patients, that their chance of having chronic leg or groin pain is less than one percent?
A My own personal experience with my patients, having followed them in the long-term.
MS. FITZPATRICK: If we can pull Saradi. Maybe I'll take a quick look while we're doing that. We'll take a break.
(Whereupon, a brief recess is taken.)
MS. FITZPATRICK: Let me mark this as Exhibit 13 and this is the article by Dr. Zhang that you had discussed.
(Exhibit Fromer 13, Retropubic Tension-Free

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Vaginal Tape and Inside-Out Transobturator Tape: A long-term randomized trial, marked for identification.)
BY MS. FITZPATRICK:
Q Dr. Zhang's article was the one that you had referenced as an RCT that had a primary end point of safety. Having looked at the article, is that still your opinion concerning this article?
A Well, they phrased it in a different way. The primary outcomes where the proportions of patients with long-term postoperative complications, which is another word for safety.
Q Okay. And this is the only RCT that you know of that had that primary outcome of safety, correct?
A It -- yes. And for stress incontinence or pelvic floor repair.
Q So just looking at this article, this looked at both the TVT and the retropubic group and an obturator group, correct?
A Correct.
Q And it found that there were long-term complications in 43.1 percent of patients who had the TVT device, correct?
A That was in the TVT, yes.
Q That's not rare, is it?
MS. KABBASH: Objection.

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A I never said 43 percent was rare.
BY MS. FITZPATRICK:
Q And do you tell your patients that they have greater than 40 percent chance of having a long-term complication associated with the TVT?
A I do not because I don't necessarily believe that the 43 percent is necessarily related to the TVT. This is a long-term study, over 95 months, which, you know, for example, de novo overactive bladder, that is something that can happen as related to the sling, but it's also something that can happen with the natural history of overactive bladder and in an aging population of women.
Q Well, let me get this on the record.
The TVT-O, there was a long-term complication rate of 27.4 percent, correct?
A Correct.
Q Do you counsel your TVT-O patients that they have a greater than 25 percent chance of having a long-term complication associated with the TVT-O?
A No. Because we break complications down. So, for example, voiding complaints after slings that persist, in the long-term, is something that is discussed because that, as you said, is not rare. It is less common than more common and can occur in up to 20

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percent in any anti-incontinence procedure. So that is discussed broadly in terms of having any kind of surgery for incontinence.
Q Okay.
A The slings being included.
Q So let me take a look at, if I'm reading this correctly, on page 107 of this article, it looks like what Dr. Zhang's group found is that 20.6 percent of the TVT group had de novo voiding systems, that means new, correct?
A Correct.
Q And it found that 11.29 percent of the TVT-O group had de novo voiding symptoms following placement of the TVT-O, correct?
A Can you give me a second? Which line -- you're looking at the chart, the table?
Q Uh-huh.
A And de novo voiding symptoms, 20.69 percent in the TVT group; 11.29 in the TVT-O group; both within range for what we would expect for the de novo voiding since this would be for any anti-incontinence procedure.
Q So you don't think that's got anything to do with the TVT or the TVT-O?
A Again, I think that any anti-incontinence procedure carries a risk of de novo overactivity. Do we

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know what causes it? Not necessarily. There are many theories about that, but we don't know that it's the actual sling. We don't know that it's the proximity that we operate to nerves in any of these anti-incontinence procedures.
And this is -- again, this is a rate that all surgeons know. This is something that is a well-known complication of any anti-incontinence procedure including Burches and autologous fascial slings.
Q So you think there is a 20 -- according to the literature, there is a 20.69 percent chance, or somewhere around that, of de novo voiding symptoms following an autologous fascial sling procedure?
A I'm sure we can find a study that goes up that high, but we can look at other studies. We can look at the Schimpf to see what they found.
Q Okay. Let's look at -- let's do that. Let's look at Schimpf.
Now, would you rely on Dr. Schimpf's article to give you the rates of adverse events for autologous fascial slings?
A That's a good question. I would probably be more likely to rely upon the AUA guidelines for the treatment of stress incontinence that did a more historical analysis. Because, I think in recent years,

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autologous fascial slings have fallen out of favor for obvious reasons. So I don't know that they're -- you know, this is -- that's not something that I was truly looking at and relying upon for this, but, however, in my report I believe I did cite the AUA guidelines on stress incontinence for that.

Q Does Dr. Schimpf, in her article, report anywhere on the rates of adverse events associated with the autologous fascial sling?

A Well, she talks about pubovaginal slings.

Q Is it your assumption that when she talks about pubovaginal slings that she's talking about autologous fascial slings?

A It's my assumption it's included in there.

Q So if we go back and you look at table 1 on page 71.E3, and you'll see about halfway down the page, it says pubovaginal sling versus Burch.

A Uh-huh.

Q And you'll see an article by Dr. Culligan in 2003, and there she has considered a Gore-Tex sling as a pubovaginal sling, correct?

A Yes.

Q And Gore-Tex is no longer used as a surgical intervention to treat stress urinary incontinence, correct?

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A Yes, because of complications.

Q Right. It's got a very high rate of complications, correct?

A Correct.

Q And so if you're including a Gore-Tex study in with autologous fascial slings, it's necessarily going to skew the numbers because of the high rates of complications associated with Gore-Tex, correct?

A Yes, I would agree with you.

Q And Dr. Culligan's article is footnote 20 in Dr. Schimpf's article, correct?

A Correct.

Q And if you look then at table 3, and you look at the randomized control trials and adverse event studies, you see the footnotes up top? It's between footnotes 9 and 57 --

A Uh-huh.

Q -- which includes 20, correct?

A Uh-huh.

Q Which includes Dr. Culligan's study, correct?

A Okay.

Q Do you agree with me?

A Yes.

Q So you wouldn't rely on these rates of adverse events associated with a pubovaginal sling to accurately

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reflect the rate of those adverse events associated specifically with an autologous fascial sling, correct? They're not synonymous here?

A No, I wouldn't. However, the flip side is also skewing data in that they've included some TVT SECUR in the midurethral sling; that is getting mixed into the retropubic. So if you look -- continue on table 1, you can see all the comparators, TVT SECUR being included in the analysis.

Q Now, show me where that is.

A Table 1.

Q Okay.

A Page 71.E5. Mini-sling versus any other sling.

Q Okay. And that is studies that are looking at the safety or efficacy of the mini-sling?

A Right.

Q Versus any other sling.

A Right. She did not lump the mini-slings, you're right. She did not lump the mini-slings with the retropubic and obturator slings, so it was a separate line that would bring down the mini-slings.

Q Okay. So it's really -- here, it's the pubovaginal, at least from what you can see here, the pubovaginal adverse events here can't be correlated

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solely to an adverse event associated with an autologous fascial sling, right?

A Well, can we go back to that table? How many patients were included in that Gore-Text trial? We're looking at 17 patients out of a total of how many patients who she's including pubovaginal sling. We can calculate this, but we would have to see what percent to see how skewed it would be. I would look at that.

Q Right. But you would agree that the way to calculate the complication or adverse event rate with an autologous fascial sling, is to look at the autologous fascial sling and not to include either the Gore-Text or the dura mater, which is not a autologous fascial sling too, correct?

A Yes.

Q And Dr. Schimpf hasn't done that?

A No. Although, again, the significance of it depends upon, you know, if it's .1 percent of the patients, is that very significant? If it's 80 percent of the patients, it's obviously significant.

Q But you don't know?

A No, but I can figure it out.

Q But you haven't, right?

A No. But I -- I didn't say that I was relying on this. I said that I would rely on the AUA Guidelines

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for pubovaginal sling.
Q So I just wanted to establish you're on the same page with Dr. Schimpf.
Now, going back to Dr. Zhang's article, there is a rate here, table 2, of de novo dyspareunia, and that means new onset dyspareunia, of 5.17 percent with the TVT and 8.05 with the TVT-O, correct?
A Correct.
Q Do you counsel your patients on those statistics?
A I do counsel my patients on de novo dyspareunia.
Q And what rate do you tell them to expect?
A So I usually tell them around five percent or less.
Q Tape exposure, now, that is an erosion or extrusion, correct?
A Well, it depends on the definition, but it means that -- tape exposure means that you can visualize the tape through the epithelial.
Q And the epithelial would be the vaginal epithelial, so the tape is coming through the vaginal wall and exposed into the vagina, right?
A It's the visualization of it, correct.
Q So we've got a 3.45 percent with the TVT and

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an 8.05 percent with the TVT-O. What do you counsel your patients on is the rate of tape exposure for the TVT?
A For the TVT itself?
Q Uh-huh.
MS. KABBASH: The retropubic?
MS. FITZPATRICK: The retropubic, yeah.
THE WITNESS: Yes. I --
MS. KABBASH: I just want to continue my standing objection. Go ahead.
A Okay. I counsel my patients that it's less than five percent.
BY MS. FITZPATRICK:
Q And what do you do with the TVT-O?
A The same.
Q And that's inconsistent with this article, correct?
A That is.
Q Okay.
A But not inconsistent with the data that I've looked at over the last year and a half and my overall experience of operating on hundreds of patients, and understanding that there is a technical component to this, that it's operator-dependant.
Q So let me just -- what seems to me is when

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you're faced with -- there's lots of --
Let me put it this way: There's lots of studies out with this different rates of complications associated with each of these devices, correct?
A Correct.
Q And when you're counseling patients, you tend towards the lower rate, the lower reported rate of complications rather than the higher reported rate of complications?
MS. KABBASH: Objection.
A Not true.
BY MS. FITZPATRICK:
Q But you're not doing it in consistency with the only randomized controlled trial that was looking at long-term safety complications associated with these devices, correct?
MS. KABBASH: Objection.
A Just because they -- this was the only study that looked at safety as a primary outcome -- doesn't debunk the large volume of data on safety and efficacy in patients -- on thousands of patients in hundreds of articles that I've cited.
BY MS. FITZPATRICK:
Q So you think this one's an outlier?
MS. KABBASH: Objection.

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A No, I didn't say that.
BY MS. FITZPATRICK:
Q Then I'm trying to understand what it is. Because every time we look at statistics, you keep telling me it's at the lower rate. It's at the lower. It's at the lower rate. And you seem to be disregarding the reported studies that have the higher rates of complication. I'm trying to figure out why you do that.
A No, I'm -- I'm not disregarding that. I'm taking it into consideration. This study came up because you had asked me if there was a study that looked at safety as an end point. And so I said yes. In fact, there is a study that looked at safety as an end point. And this is how this article came about. This is one of many articles that looks at TVT versus TVT-O and there's obviously a range.
Q Okay.
A And then there's my own personal experience as well.
Q Let me ask you quickly with respect to Dr. Schimpf's article again. If we can go to table 4. And if you go about halfway down, it says retropubic versus obturator midurethral slings, correct?
A Correct.
Q And it says that retropubic slings result in

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lower rates of sling erosion, need to return to the operating room for treatment of sling erosion, groin and leg pain, and vaginal perforation; do you agree with that?
A I agree with the groin and leg pain. I agree with vaginal perforation. And, as a result of vaginal perforation, I agree with the rates of sling erosion and need to come to -- need to return to the operating room.
Q Okay. So you agree with that?
A Correct.
Q Okay. And with transobturator midurethral slings result in shorter operative time, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less overactive bladder systems; do you agree with that?
A Yes.
Q And so this goes back to the discussion that we were having that there are differences in the risk/benefit profile of the TVT versus the TVT-O procedures, correct?
A Correct.
Q Now, I want to go back to the instructions for use. And you've looked at the instructions for use associated with both the TVT and the TVT-O systems, correct?

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A Yes.
Q And you've offered some opinions on those instructions for use, correct?
A Correct.
MS. FITZPATRICK: Can we mark the TVT instructions for use -- and I apologize. It's very small print -- as 14, I believe, and the TVT-O as Exhibit 15?
(Exhibit Fromer 14, Gynecare TVT Instructions for Use, marked for identification.)
(Exhibit Fromer 15, Gynecare TVT Obturator System, marked for identification.)
BY MS. FITZPATRICK:
Q Now, you've seen both of these before, correct?
A Which year is this?
Q These are the pre-2015.
A Okay. Yes.
Q This TVT is 2009. Do you see that right down here?
A Right.
Q And then, I believe that the Gynecare was 2010.
A This looks like --
Q 2008?

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MS. KABBASH: Just to put on the record for the benefit of both of you, don't lend any credence to copyright dates. The dates that they're in use would be according to the chart that we have produced in the litigation. So that's what -- and I'm not doubting what you're saying that it would be in effect in 2009, but I'm just saying, don't go by copyright dates on anything. Our chart that has been produced in the litigation is which governs any use dates.
MS. FITZPATRICK: Okay. Fair enough.
BY MS. FITZPATRICK:
Q And you've looked at the TVT-R IFUs over time, correct?
A Uh-huh, yes.
Q And you know that the changes to that TVT IFU came in 2015, correct?
A That's correct.
Q So you've seen the pre-2015 and the post-2015, correct?
A Yes.
Q And it's the same with the TVT-O, that there's pre-2015 IFU and then the major changes were made in 2015, correct?
A Yes.
Q And you also understand that the cases at

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issue in Wave 1 of this litigation all involve pre-2015 implants?
A Yes.
Q Do you understand that? Okay.
So we've already established, and you've agreed with me, that there are different risk/benefit profiles to the TVT and the TVT-O that are supported by your experience and by the literature, correct?
A Yes.
Q And I'm wondering if, in looking at these instructions for use, I'm a physician looking at these, where I could see the difference between the risk profile associated with the TVT versus the risk profile associated with the TVT-O.
A Why don't you know that already, Doctor?
Q I'm asking you what Johnson & Johnson told physicians. I understand your position that the medical device manufacturer is off the hook. It's completely on the medical community. I'm just asking you, though, putting that aside and looking at these, where could I, as a physician, see the differences between the risk profiles associated with the TVT and the TVT-O as communicated to me by Ethicon?
MS. KABBASH: Objection. Mischaracterization.
A Okay. So we would look in the adverse events.

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Do you have it turned to a specific page for me or do you want me to find it?
BY MS. FITZPATRICK:
Q I'm asking if you're aware of anywhere in these IFUs that reflect a different risk profile for the TVT versus the TVT-O.
A So here we go. On this page, you see a picture of the implant going through the transobturator, going through the obturator canal and coming out the groin. There I am, okay. This patient is going to have postoperative groin pain at the site where it's coming out. Okay.
I'm going to avoid having a bladder injury because I know where the bladder is. I know my pelvic anatomy, and I'm going to avoid hitting the bladder. So I know that I'm not -- I'm very unlikely to have a bladder injury through this technique looking at the diagram.
Q Maybe you're not understanding my question and I don't want to -- I apologize if I made it unclear.
The IFUs contained contraindications and warnings and precautions, right, including an adverse event. So let's, for example, start with the TVT-O. I think you mentioned in one of your answers that sometimes athletes and marathon runners, et cetera,

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don't want to take the risk of the transobturator procedure because of the increased potential for a chronic leg or groin pain that could affect them, correct, something along that line; did I get --
A Yes, relative to -- I'm sorry.
Q -- that sort --
A Yes. Relative to a retropubic TVT, for example.
Q Can I find that in here? Is there somewhere in here that tells me that?
MS. KABBASH: Objection.
A Well, again, I'm a doctor. I'm not somebody that's walking off the street. I don't need somebody to say --
BY MS. FITZPATRICK:
Q I understand you and I are going to disagree on the importance of IFU. You got your record on that. The IFU still exists. So I'm not asking you your opinions whether they're important or not.
I'm asking your opinions on what is contained in them regardless of whether you think they matter or not?
MS. KABBASH: Objection. Mischaracterization.
BY MS. FITZPATRICK:
Q Is the TVT-O contraindicated or it's indicated

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anywhere in the contraindications or warnings or precautions or adverse reactions, that there's a greater risk of chronic leg and groin pain in what you've observed with athletic or active women?
MS. KABBASH: Objection.
A I never said that. I never said that it was -- there was an increased risk of leg pain specifically for active women. I said that active -- and I don't mean active women. I mean people who make a living out of being physically active that have concerns about having any kind of surgery on their legs. So I just want to clarify what I previously said.
Transient leg pain, lasting 24 to 48 hours, may occur and can usually be managed with mild analgesics.
BY MS. FITZPATRICK:
Q Does that say "chronic"?
A No.
Q So where does it tell me about the chronic?
A Punctures or lacerations, vessels, nerves may occur during needle passage and may require surgical repair.
Q Do you think that's specific to the TVT-O?
A No.
Q So that's all I'm asking you about.

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Could a physician, by looking at the TVT-R and the TVT-O instructions for use, discern the differences in the risk profiles for these particular devices through what Ethicon has said here?
A Yes. I do believe that, based on the diagrams that are here and based on the expected knowledge of the surgeon implanting these devices.
Q I'm not asking you about the expected knowledge, and I know you keep wanting to go there. And I think you keep wanting to there because you know this stuff isn't in here.
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q I'm asking you about the language in the IFUs. If there's something in the language of these IFUs that tells doctors that there are different risks associated with the TVT versus the TVT-O, does it exist in these IFUs?
MS. KABBASH: Objection to editorial statement of counsel. Asked and answered.
A So in the TVT IFU, it suggests that cystoscopy should be performed to confirm bladder integrity or recognize the bladder perforation which is a specific complication associated with the TVT, more common in the TVT than the TVT-O.

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I do believe that -- before I say "I believe," it says, "Cystoscopy can be performed at the discretion of the surgeon." So the company is saying it's optional because the risk of bladder perforation is much less than the risk of bladder perforation with the retropubic TVT.
Q Is that the best you got to defend the IFU?
MS. KABBASH: Objection. Argumentative.
BY MS. FITZPATRICK:
Q Keep going.
MS. KABBASH: Hang on. Let me get my objections on the record.
Argumentative. And I'm just -- argumentative. Go ahead. She can answer.
A Okay. So again, another difference in technique associated -- in order to alert the physician to the fact that bladder injury is a potential -- is using the catheter guide, which is not employed in the TVT-O; again, alluding to the higher risk of bladder perforation with a retropubic TVT.
And again, the leg pain is here and not here. Transient -- sorry.
MS. KABBASH: Can you be more specific for the record?
THE WITNESS: The transient leg pain that's

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stated here is not stated -- the transient let pain that is stated in the TVT-O IFU is not stated in the TVT IFU.
MS. KABBASH: Fidelma, I don't know what your intentions on timing are, but it's almost 1 o'clock and I want to feed my witness.
MS. FITZPATRICK: Okay.
MS. KABBASH: Including you.
MS. FITZPATRICK: Okay.
BY MS. FITZPATRICK:
Q Does it say anywhere in the -- are there words in the TVT IFUs that say there's an increased risk of bladder perforation?
A With the TVT relative to the TVT-O?
Q Uh-huh.
A No.
Q Okay. Does it say in the TVT-O anywhere, that there's an increased risk of chronic leg and groin pain relative to the TVT?
A The word "chronic" is not used in association with leg pain.
Q And you'll agree with me that the contraindications, warnings, and precautions and adverse reactions are largely the same between the TVT IFU and the TVT-O IFU, correct?
MS. KABBASH: Objection.

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A There are similarities, but still there are differences.
BY MS. FITZPATRICK:
Q They're more similar than different, don't you think?
MS. KABBASH: Objection.
A They are similar, but it's the same tape, just a different delivery system.
BY MS. FITZPATRICK:
Q Okay. And you agree with me that that delivery system and the placement, as we've already established, creates separate risks, correct?
A Yes.
Q And that's what you counsel your patients on, correct?
A Correct.
Q And if I were looking for it in these two IFUs, I can't find that information?
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q Right?
A That's not correct. I can find that information here.
Q You can find that information? Okay. That's interesting. We'll leave it at that.

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Do you want to stick with that answer?
MS. KABBASH: Objection. Don't answer that.
BY MS. FITZPATRICK:
Q I want to know.
MS. KABBASH: All right. Answer it.
A Okay. The information that I get from this involves every page of this, not just the words that are explicitly stated.
BY MS. FITZPATRICK:
Q Okay.
A Because I am not a layperson sitting here reading this. I'm a surgeon who does pelvic floor surgery.
Q Okay. Do you know what the difference between laser-cut and mechanically-cut mesh in the TVT and the TVT-O are?
A Yes.
Q Tell me what those are.
A I mechanically-cut mesh. It's cut by a machine and laser-cut mesh is cut by a laser.
Q What are the different risk profiles?
A There are no different risk profiles that have been written about in the literature, to my knowledge. There's been no head-to-head study that I know of that compares efficacy or safety.

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Q Are you aware of any internal Ethicon documents which reflect on different risk profiles between the laser-cut and the mechanically-cut mesh?
A I read a lot of pontification with no data to support it that was reliable.
Q So you believe the internal Ethicon documents concerning the differences in the risk profiles between the mechanically-cut mesh and the laser-cut mesh are not reliable; is that right?
MS. KABBASH: Objection.
A The statements that I had read -- and I'll tell you specifically what I'm talking about, I recall an e-mail about fraying in the mechanically-cut mesh. And in my opinion, there's no data to support that there's any adverse outcome from fraying in mechanically-cut mesh. And that was pontification on the part of surgeons as well as possibly whoever the person in the company is that I read the e-mail.
BY MS. FITZPATRICK:
Q Is there data to support your conclusion that there is no difference between the risk profile of the laser-cut mesh and the mechanically-cut mesh?
A There is no data to support it or to not support it. It doesn't exist. And largely, the original TVT was laser-cut and the data that we have on

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that is long-term.
Q Really?
A I'm sorry. That was a typo.
Q Okay.
MS. KABBASH: Verbal typo?
A The original TVT was mechanically-cut -- I need lunch -- was mechanically-cut. And, therefore, we have -- we have a large body of data on mechanically-cut mesh.
BY MS. FITZPATRICK:
Q What data do you have to support your hypothesis that the laser-cut mesh performs the same as the mechanically-cut mesh?
MS. KABBASH: Objection.
A There is no data to support that one is better than the other.
BY MS. FITZPATRICK:
Q Okay.
A Or that one is worse than the other.
Q What I wanted to know, though, what data do you have to support your hypothesis that the laser-cut mesh performs the same as the mechanically-cut mesh?
MS. KABBASH: Objection.
A Over the years, we have -- our hospital has switched from a mechanical-cut mesh to a laser-cut mesh.

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I have noticed no difference in outcomes with respect to either one.
BY MS. FITZPATRICK:
Q Okay. Let me ask you the same question.
What data do you have to support your hypothesis that the laser-cut mesh performs the same as the mechanically-cut mesh?
A There is no data to support one over the other.
Q And you can't just assume that the data on the mechanically-cut mesh is transferable to the laser-cut mesh, can you?
MS. KABBASH: Objection.
A Most of the slings that are on the market today, I believe, are laser-cut. So if you look at laser-cut mesh outside of Ethicon, you see the same rates of complications in efficacy rates with other polypropylene slings that are laser-cut.
BY MS. FITZPATRICK:
Q Which ones do you think are laser-cut?
A The Boston Scientific product is laser-cut.
Q Are you sure?
A Yeah.
Q Could it be that the Boston Scientific is laser-cut suburethrally and it's not laser-cut? It's

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mechanically-cut? And that the rest of the sling is mechanically-cut?
A That might be the case, but the relevance is where it lies -- I assume that what you're getting at is the relevance with respect to extrusion data.
Q Are you aware of reports in the literature, that the Boston Scientific Advantage Sling is two times stiffer than the Ethicon TVT mechanically-cut?
A I don't see how the stiffness of the mesh is related to the cut of the mesh.
Q You don't see how a laser-cut, where it melts the edges of the sling, can lead to an increased stiffness in the mesh over a mechanically-cut?
A It was my understanding that the whole mesh was not placed under a laser, that just the edges are lased. So I don't -- again, it doesn't make complete sense to me. That's not intuitive to me that cutting the edges of the -- of the mesh is going to result in stiffness. It could be stiffer because it's stiffer.
Q Well, let's say that.
So you wouldn't say that a mesh that is two times stiffer than the Ethicon TVT, would necessarily have the same risk profile, correct?
A I don't know the answer. I'd have to look at clinical head-to-head trials to see.

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Q So you don't know? You don't have data to support the opinion right now, correct?
MS. KABBASH: Objection.
A I haven't researched the Boston Scientific sling nor do I use it. So I can't talk to the safety and efficacy especially in comparison to other slings.
BY MS. FITZPATRICK:
Q Fair enough. How do you know whether you're using a mechanically-cut or a laser-cut TVT?
A We look at the box. In fact, I didn't know up until yesterday when I looked at the box.
Q Okay. So prior to -- I don't know what today is. Prior to March 28, 2016, you didn't know when you implanted a TVT into a woman, TVT or a TVT-O, whether you were using a laser-cut or mechanically-cut, correct?
A That's because I believe it's irrelevant.
Q And that's not based on any data, though?
MS. KABBASH: Objection.
A There is no -- there is no data to support one is better than the other.
MS. FITZPATRICK: Okay. Do you want to take a quick -- if we can do a quick lunch break?
MS. KABBASH: Yes.
MS. FITZPATRICK: I'll get through the Prolift pretty quickly, and then we can put on to

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Mrs. Sacchetti's case.
(Whereupon, a luncheon recess is taken.)
BY MS. FITZPATRICK:
Q I'm just going to ask you a few questions about the Prolift, and then we'll move on to Mrs. Sacchetti's case.
Do you know what Ethicon did to evaluate the safety of the Prolift before they put it on the market?
A I believe that they had a TVM study, a group of French surgeons, and an American arm that did some preliminary safety and efficacy studies.
Q And do you believe that what Ethicon knew about the safety and efficacy of the Prolift, they learned prelaunch, should have been conveyed to physicians who were first implanting the Prolift into women?
MS. KABBASH: Objection.
A I think whatever the company knew about the data, when they were disseminating it to other individuals, should have been disseminated.
BY MS. FITZPATRICK:
Q Okay. And that's so that those women who were getting implanted with the Prolift could make a decision on whether they wanted to accept those risks or not when getting implanted with the device, correct?

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A Sure.
Q Do you know what Ethicon's internal criteria was for whether a woman was a candidate for a Prolift?
A In terms of the degree of prolapse?
Q In terms of the degree of prolapse or just the patient demographics.
A I don't know.
Q Okay. And would what Ethicon knew about the Prolift, prior to launch, be of any significance to you in forming your opinions in this case?
A Yes. I think that that's important to some degree, depending upon what it is.
Q Did you ask the attorneys who retained you to give you any information on what Ethicon knew or didn't know about the Prolift device before it was launched?
A I didn't ask for it, but they provided me with a binder of materials.
Q Okay. And --
A An electronic binder.
Q And those included internal Ethicon documents, correct?
A Yes.
Q And were those selected by the attorneys in the case?
A Yes.

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Q Did you give them any criteria or tell them the types of documents that you wanted?
A No.
Q When you looked through those documents, did you ask them for any additional documents or any other things that came to mind when you looked at them?
A I don't think so.
Q And what significance did you attach to the internal Ethicon documents that you were provided at the time that you prepared your report?
A I think that there was some data that was reported, that was eventually published, that was not horribly inconsistent with any of the data that we currently have. There were a lot of e-mails and communications back and forth that didn't hold much significance to me.
Q And why didn't they hold much significance to you?
A These were conversations between people and they didn't -- it didn't have any scientific basis for whatever. I assume that that's the reason why I didn't hold credence to it. There was no -- nobody was backing up anything about scientific data.
Q Did you see any documents where physicians were reporting complications or adverse events to

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Ethicon associated with the Prolift?
A I may have, though none of them come to mind. I reviewed a lot of documents, so it's hard to keep it straight.
Q Do you think that what the physicians were reporting to Ethicon, concerning the Prolift, would be important for understanding how the device was actually working in the real-world, is what I think you called it?
A What do you mean by -- what specific things are you referring to?
Q Anything that a physician would be reporting to Ethicon concerning the safety or complications associated with the product. Is that significant to you?
A It depends on what they're reporting.
Q And what do you mean by that?
A So I mean, what comes to mind is the -- you know, I'm thinking more of TVT-O because that's what comes to mind when you talk about physicians reporting things that are not necessarily clinically significant, that some doctors didn't like the way that they saw when they -- when the material was dyed blue that they saw blue fraying. And in my opinion, that's clinically insignificant. But people didn't like it because they

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didn't like the appearance; so that's an example of a complaint that doesn't really hold credence. So that's why there are differences depending upon what the complaint is. Somebody can say, You know, I don't like the way this feels. That doesn't necessarily hold credence to it.
Q If physicians are reporting actual complications and poor clinical outcomes for patients, do you believe that's significant?
A Again, it depends on the numbers. It depends on how they're reporting them.
Q But you realize at the beginning, when Ethicon first put the Prolift on the market, that much of the information about complications would come from anecdotal information from physicians or from case studies, correct?
A I don't know the answer to that question, but that's possible.
Q Do you know how much data -- when did you start using the Prolift?
A I want to say -- when did it -- when did it -- it came out in 2005?
Q Uh-huh.
A I want to say I started using it in 2006. I recall I did my training in 2006, and that's probably

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when I started using it, if I had to guess.
Q What data did you rely on to satisfy yourself that it was both safe and efficacious for your patients?
A I was relying upon a lot of what was didactically given at -- at the ProfEd.
Q And that was the training course by Ethicon, correct?
A Yes.
Q And so you would be relying on them to give you complete and full information about all of the risks associated with the device so you could make a decision on whether to use that, correct?
A Correct.
Q And you believed that Ethicon had a duty to you and to others, who it was training, to give full information on the risk profiles, correct?
MS. KABBASH: Objection.
A I -- I believe them to give a -- give the honest data on the outcomes.
BY MS. FITZPATRICK:
Q What data was available at that time on the outcomes?
A I don't remember. I don't know.
Q So you're not sure what data, if any, you were relying on?

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MS. KABBASH: Objection.
A It was a long time ago when I started using it, so it's hard to know.
BY MS. FITZPATRICK:
Q But you were one of the early adapters to the Prolift. Correct?
A I don't know. I mean, I -- I started adapting it, what, a year after? I don't know if you would consider that early or not.
Q And you don't know whether there was any data available by way of clinical trial that would support the safety or efficacy of the device at that time, correct?
A I make the assumption that there were. I wouldn't be operating on something without any clinical data.
Q And the same with the TVT-O. Did you rely on specific clinical data when you began to use that product?
A Again, I'm sure that there were -- there were trials and there was data available; otherwise, I would not have been using it.
Q And when did you start to use the TVT-O?
A TVT-O came out in '04.
THE WITNESS: Yes?

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MS. KABBASH: Yes. If you don't mind me telling her.
MS. FITZPATRICK: Yes. I thought I'd have it my head, too.
A I mean, it was probably soon after it came out. '04 or '05 I would -- again, I would guess.
Q And it's your recollection that you would not have used that TVT-O device, absent any clinical data that you could rely on for the clinical safety and efficacy of the device, right?
A That's correct.
Q Now, in your report you say that the medical literature on Prolift -- if you look at page 29 to 30 of your report -- I don't want to put words in your mouth -- that the medical literature on Prolift shows it provides significant benefits to well-selected patients with a reasonable risk profile, particularly when used by surgeons who are experienced with the device.
So I want to -- do you see that?
A Uh-huh.
Q So I want to break that statement down.
What are the criteria for the well-selected patients that you...
A Good question.
So there are patients where other surgical

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procedures for prolapse may not be a good choice. For example, take a patient who has failed the native tissue repair, a patient who has multiple abdominal surgeries, may even have a bowel diversion for which you don't want to do a transabdominal route and you don't want to repeat another native tissue repair. This would be a patient that I -- that I would strongly consider for a mesh repair.
Q Would you consider a native tissue repair to be kind of the first line in a pelvic organ prolapse repair?
A Not necessarily, no.
Q So then there must being other well-selected patients that you're referring to beyond patients who've had a prior failed native tissue repair?
A Right. So patients who are concerned about failure with a transvaginal procedure -- patients who want a transvaginal procedure, and they are concerned with failure both subjective and objective.
Q Anything else?
A No. I mean, I think that pretty much limits the pool of patients that opt to use transvaginal mesh at this time.
Q Okay. What do you mean by "a reasonable risk profile"?

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A Comparable to other prolapse procedures.
Q I don't understand that.
A Comparable to -- so this has a -- my statement here is that Prolift shows that it provides significant benefit to well-selected patients with a reasonable risk profile. A reasonable risk profile is one that has a similar -- not necessarily a similar risk profile, but within the range of other procedures done to correct prolapse.
Q Okay. So you believe that the Prolift has a similar risk profile to a native tissue repair?
A No. There are different risks and different benefits to each. However, in terms of percentages, that -- that I would consider to be acceptable or that a patient might consider to be acceptable.
Q Okay. So do you believe that the risk profile of the Prolift is within the range of the risk profile for other native tissue repairs?
A Yes.
Q And you'll agree with me that erosion is a unique risk to the mesh procedure, correct?
A Yes and no. So there -- there are reports and incidents of exposure of biological tissue, exposure of suture material that's used in native tissue repairs as well, but exposure of mesh and erosion of mesh is a

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complication exclusive to mesh.
Q Do you believe that a suture erosion from a native tissue repair causes the same degree of a complication as the erosion of a polypropylene mesh?
A It can be. It can be. In terms of volume, it can be just as small. An exposure can be just -- from a mesh product, can be just as small as a loop of suture material dangling from the vaginal wall after a sacrospinous fixation.
Q So you see no difference in the relative risk of erosion presented by the use of a Prolift versus a suture in a native tissue repair? It's the same thing?
MS. KABBASH: Objection.
A No, I didn't say that.
MS. FITZPATRICK: Hold on. Let her object. Go ahead.
THE WITNESS: I said it can be, and other times it's not. Other times, the mesh can pose -- can pose more of a -- a morbidity associated with it than a suture, but there's a range. Exposure is not just exposure. There's small exposures. There's larger exposures.
BY MS. FITZPATRICK:
Q And then, what happens to women whose surgeon is not experienced with the device?

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MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q I'm just looking at your page 30.
A Yeah.
Q When used by surgeons who are experienced with the device. What happens to surgeons who are not experienced?
MS. KABBASH: Objection.
A So what I'm alluding to is certain studies that support that higher surgical volume may lower complication rates. And I think that this is not exclusive to Prolift. This is -- this is something that we see with any surgical procedure, including robotic sacrocolpopexy, robotic prostatectomy. There's always a learning curve. So outcomes are generally better when you're at the top of the learning curve than when you're at the bottom.
BY MS. FITZPATRICK:
Q Do you believe Ethicon should only have made its Prolift available to surgeons who are experienced in the device?
A I don't believe that it is Ethicon's responsibility. But I do believe that it, in many circumstances, it's up to the hospital or even the surgeon to decide whether or not they can use products

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for complex reconstructions. I don't think that's up to the company.
Q Now, you got trained on this device in 2005 to 2006, correct?
A Probably, yes.
Q Okay. And there came a point in time where you had patient number 1, the first person that you implanted a Prolift in, right?
A Yes.
Q And your experience now is very significantly different than your experience was at the time?
A Correct.
Q Do you believe that you should not have been using the Prolift at that time because you were not a surgeon who is experienced with the implant of the Prolift device?
A No.
Q Okay. Then tell me how that works.
A You tell the patient there's something new on the market. You'll be my first patient. And these are the risks associated in high-volume users and patient -- when I do something for the first time on anybody, they know that they're the first person.
Q Do you believe that physicians should be telling patients that there are greater risks and

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complications for low-volume users over high volume users?
A I think that that's expected because, again, I think that the learning curve is a well-known phenomenon that occurs for any surgical procedure that we do.
Q And you agree with me the only way you can get to the top of the learning curve is by actually doing the procedure, right?
A That's correct.
Q So anybody who is now well-experienced with the device, at one point, had no experience with the device or little experience with the device, right?
A That's correct.
Q And it's trial and error. You keep doing it, and the more times you replicate the procedure, the better you, as the surgeon, get with it, correct?
MS. KABBASH: Objection.
A Well, I wouldn't use the words "trial and error." You learn things over time, not by error necessarily, but by just learning that you can have better outcomes with certain tech -- certain techniques. And, again, this is why we have training programs now, to train people.
Q How long was the training program that you went to? Was it a one-day didactic and a one-day

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cadaver?
A Things are different now than they were then. Okay. So now, it's my personal opinion that it's up to the surgeon and up to the training physicians in residency and fellowship programs, to adequately train their residents to be able to do this in the real-world and not have to go out there and learn it on their own or learn it from -- or learn it from, you know, ProfEd.
Q But when you started doing this in 2005 and 2006, you were learning it through an Ethicon procedure. And did you learn from other surgeons that you were working with at the time?
A There were other surgeons that were doing Prolift, I believe at Hackensack, that I was observing. And I did go to cadaver courses, as many as I could, to get further acquainted with the anatomy required to do Prolift. So I did -- I did more homework than just going out and doing it.
Q Now, one of the things that you talk about in your report is this concept of tensioning, do you recall that, of over-tensioning the device?
A Okay.
Q Do you recall saying that?
A Well, I know it's in the surgeon's monograph that over-tensioning can result in pain, contractions,

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bunching, so I may have put that in the report.
Q How does a physician -- let me step back from that.
Tensioning can differ -- tensioning the device is an art rather than a science, correct?
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q Meaning that you learn how to tension the device in individual women through your experience in implanting the device, correct?
A Not necessarily. So the way I was trained was to make sure that there are two fingers in the fornices of the vagina holding the mesh in place, while you're tensioning so that you don't over-tension the device. This is a means of preventing the mesh from getting too tight under the bladder or too tight in the -- at the obturator foramen.
Is that quantitative? Is there -- is there a way of quantitating that? Not necessarily.
Q Have you ever over-tensioned a device?
A Inadvertently?
Q Well, I'm assuming you didn't do it intentionally if you did.
A Correct. Not that I recall.
However, I do train residents and so there --

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these things can happen, and these things are identified. So I -- I have seen the potential for that in -- in my residents.
Q And you don't believe that the mesh itself in the Prolift, actually contracts invivo, do you?
A Well, I believe that the tissue around the mesh contracts and the mesh contracts with the tissue because the tissue is integrated into the mesh.
Q And you'd agree with whether it's the mesh itself contracting or the scar tissue around it, mesh contracting, that that can cause complications such as pelvic pain and dyspareunia?
A It's been cited. I -- I have not found anything that is showing causation, that retraction of mesh directly causes pelvic pain and dyspareunia.
Q People scar differently, don't they?
A I don't know the answer to that question.
Q Okay.
A And I -- I -- I will also say that I don't -- I don't truly believe that people scar differently. I do know that some people form keloids, other people don't. So in that circumstance, yes, people can scar differently, I suppose.
But in terms of the pelvic floor, it's pretty -- any time I've gone back in from pathologic or

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nonpathologic reasons, it looks -- for the most part -- the same to the naked eye.
Q But this rate of -- I'm going to call it contraction, you can call it scar contraction, but that phenomenon that you're talking about, you agree that that can vary from patient to patient, right?
You don't know whether someone's scar is going to retract the mesh 10 percent, three percent or thirty percent, correct?
A I think that there's been ranges reported in the literature and there is a range. And I think that it can probably contract within that range. How narrow that range is, I'm not sure. We'd have to go to the literature.
Q And you would rely on what's reported in the literature as far as what the range of that can be, correct?
A I would rely on what we have. Whether it's reliable data is hard to know in the absence of physical measurements. So I know a lot of people are using ultrasound. There's reports of MRI. But again, the way to know is if you're physically measuring it. And I don't know that that has truly been done reliably.
Q Have you seen any articles where that was actually done though?

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A How -- how they measured --
Q That they measured how much contraction occurred.
A Possibly, but I can't recall, off the top of my head.
Q Have you seen any internal Ethicon documents where they quantified the rate of or range of contraction of mesh?
A I may have seen it in the -- in the documents as well.
Q Do you recall what that was off the top of your head?
A No.
Q Do you believe that contraction can lead to a balling up of the mesh in the pelvis?
A What do you mean by "balling up of the mesh in the pelvis"?
Q That it can contract the mesh into a ball.
A A sphere, like this?
Q Yes.
A No, I don't believe that.
Q And if Ethicon said that, you would disagree with them, correct?
A Yes.
Q And if Ethicon said that the contraction of

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mesh can cause it to fold over or wrinkle in the pelvis, would you disagree with them?
A Well, it depends on how they're making that claim.
Q So you're not sure whether that can happen or not?
A No, I'm not sure. I know that the mesh can be left folded if proper tensioning wasn't placed on it or if the technique was not done correctly. If the trocars are not placed correctly, you can definitely have bunching of the mesh that's iatrogenic or caused by the surgeon, but not necessarily that it would just magically form.
Q So you think that if the mesh is folded, it was caused by the surgeon and not through this contraction process that we're talking about?
A I didn't say that. But I do -- what I said was that the mesh can fold, and it can be -- as it -- it can be placed folded. That's one of the ideologies for identifying folded mesh when you go back in for whatever reason.
Q Okay. But I'm asking you a separate question. I'm asking you whether this contraction process that we've talked about can also lead to folded mesh?
A That I'm not sure about. I can't prove that.

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Q Do you believe that this contraction process that we've talked about can cause pain in women?
A Again, I'm not convinced of that. I have not seen any data or any scientific evidence connecting the ideology of dyspareunia and pelvic pain after these procedures directly to retraction.
Q Okay. So if Ethicon had said that this contraction can cause pain, you would disagree with them?
A It's not that I disagree with them. It's just that it hasn't been proven. It does state that in the surgeon's monograph. I don't deny that they said that.
But I have a hard time seeing the evidence to support that the two are connected because there are many things that cause dyspareunia in these patients.
Q But that's one of the things that can cause dyspareunia?
A I -- I agree with you. It might be one of them, but I just haven't seen the causation.
Q All right. And we'll get to this in a little bit.
There's lot of things that can cause dyspareunia, correct?
A Right.
Q But you agree with me that the Prolift device

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can cause dyspareunia, correct?
A The device itself or the technique?
Q The placement of the Prolift device can cause dyspareunia in a woman?
A Yes. I believe that any pelvic floor surgery, any surgery that is involving the obturator muscles, can potentially cause dyspareunia. I just -- I'm not convinced that it's the actual mesh that is the sole reason why women get dyspareunia or why there are dyspareunia rates in these surgeries.
Q But I'm not asking about a sole cause. I'm asking you about a cause, and you believe that dyspareunia can be multifactorial, correct?
A That's correct.
Q And in women who have the Prolift, the Prolift can be a cause of dyspareunia, correct?
A That -- yes, that is correct.
Q Okay. And in women who have the TVT-O, the TVT-O can be a cause of dyspareunia, correct?
A Correct. The placement of the surgery, correct.
Q And in women who have the TVT-R, that can be a cause of the dyspareunia, correct?
A Correct.
Q You had said in your report, at page 47, that

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based on your experience with over 500 surgical procedures to treat pelvic organ prolapse, it's your opinion that "Prolift was not defectively designed. In fact, to this day, I treat patients whom I believe would benefit from the product if it were still available." Is that your opinion sitting here today?
A Yes.
Q And you're aware that the Prolift is no longer available because Ethicon made the decision not to perform the required 522 studies, correct?
MS. KABBASH: Objection.
A Yes.
BY MS. FITZPATRICK:
Q And it was Ethicon's decision, and nobody else, to discontinue the product, correct?
A That's correct.
Q And if Ethicon had wanted to spend the money to perform the studies, the product may still be on the market or may even have been improved, correct?
MS. KABBASH: Objection.
A Yes.
BY MS. FITZPATRICK:
Q Do you know who Charlotte Owens is?
A No.
Q Do you know who David Robinson is?

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A No.
Q Do you know who Pete Arnaul is?
A I've never met him, but I read his name.
Q Do you know who he is?
A I believe he works at Ethicon.
Q Do you know what his position was?
A Medical director, I think.
Q Do you know when it was?
A No.
Q Do you know who Paul Parisi is?
A The name sounds familiar, so I may have come across it. Or maybe I saw it in an e-mail that you showed me or in the document that you just sent me.
Q Do you know who Aslar Kno is?
A No.
Q Do you know who Jim Hart is?
A No.
Q In preparing your report, did you read the deposition transcripts of any witnesses employed by Ethicon?
A No.
Q Why not?
A They were not provided to me.
Q Would you have been interested in reading the deposition transcripts of the medical directors at

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Ethicon who worked with these pelvic organ prolapse products?
A It depends on what was said and the significance of it.
Q Do you believe that there's something that you may have gained from knowing what Ethicon knew about the pelvic organ prolapse mesh products?
MS. KABBASH: Objection.
A Again, you know, this goes back to the earlier questioning. But it depends on what you suspect might be of issue here. So I mean, it doesn't cut -- I'm more interested in the published literature.
BY MS. FITZPATRICK:
Q Okay. Is there anything in the Ethicon documents that could change your opinion concerning the safety and efficacy of the TVT-O?
A Now that --
MS. KABBASH: Objection.
A Now that we have all the data on TVT-O?
BY MS. FITZPATRICK:
Q Yes.
A No. I think it's irrelevant because I think we have by far more data now than we ever did.
Q Is there any relevance on the Ethicon documents to your opinions concerning the Prolift?

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A The same answer holds true.
Q Okay. And is there anything in any Ethicon deposition that would have any relevance to your opinions about the TVT-O?
MS. KABBASH: Objection.
BY MS. FITZPATRICK:
Q I'm asking about depositions now instead of the documents.
A Okay. Again, no, same answer.
Q And is there anything in the Ethicon depositions that you believe would have any relevance to your opinions on the Prolift?
A Again, no. These products are now safe and effective and documented in the literature.
Q Okay. And did you read the deposition transcript of any deposition taken of Dr. Lucente in preparation?
A No.
Q Was that offered to you by Ethicon?
A No.
Q Would there be any relevance of Dr. Lucente's deposition to your opinions on the TVT-O?
A I have no idea. Again, it still has very little relevance because we have such long-term data on the TVT-O, and we have such a volume of literature on

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it. So I don't see how that would be significant.
Q And do you think there'd be any significance in reading Dr. Lucente's deposition to your opinions concerning the Prolift product?
A No.
MS. FITZPATRICK: That's all that I have on the general.
MS. KABBASH: Okay. I might have a few, a little bit of followup, so I think that probably makes more sense to do that now and start with a clean slate for Sacchetti.
MS. FITZPATRICK: That's fine.
- - -
EXAMINATION BY MS. KABBASH:
- - -
Q Dr. Fromer, I just have some follow-up questions for you.
You were asked several questions today by plaintiff's counsel about whether you had reviewed studies where safety was the end point of the study. Do you recall that line of questioning?
A Yes.
Q And I think there was some questioning regarding the Zhang study in that regard; do you recall that?

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A Yes.
Q Does a study have to have safety as its end point in order to be informative to you on safety-related information?
A No.
Q Why is that?
A All -- all the randomized control trials that we have available are not designed with the idea in mind to evaluate safety and efficacy, that although it may not be a primary end point, the data is still valuable and informative on the incidence -- complications associated with these procedures.
Q And the monitoring of complications is, in fact, part of the design of the study as is described in the published literature?
A Yes.
Q In both forming your opinions on TVT-O and Prolift, did you review randomized control trials?
A Yes.
Q And did you review meta-analyses studies?
A Yes.
Q And how do RCTs and meta-analyses fall within the hierarchy of scientific evidence?
A They're the highest level of evidence.
Q And in those RCTs and meta-analyses that you

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reviewed, were complications monitored in all of those studies?
A Yes.
Q You were asked a question about certain articles that you had added to your Exhibit B, list of materials reviewed. And in particular, you were asked, I believe in the context of your Prolift report, why you had looked at certain articles. And I'm paraphrasing your response, but you indicated something to the effect of you saw statements that were, quote, "not backed up," close quotes, by literature. Do you remember making a comment like that?
A Yes.
Q What did you mean when you said "not backed up by literature"?
A Some of my opinions that I had formed, I did not cite them into my general report on either the TVT-O or the Prolift. It wouldn't be indicated to be in there. So I went and did a literature search so that I can cite those opinions and -- and identify supporting literature to my opinions.
Q So when you went back and looked at your Prolift opinions, did you believe that they were wrong or inaccurate?
A No.

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Q Were you looking to add citations to the opinions that were already in your report?
A Yes, that's correct. But that were in my case-specific report.
Q Okay. So you wanted to find further citations for the opinions in your Sacchetti report?
A Yes.
Q Okay. Dr. Fromer, you were asked if the Prolift were still available today, would you use it. What was your response to that question?
A Yes.
Q What is your response to that question?
A Yes, absolutely. There are indications for it to this day, as I've written in my report. There are patients for whom I think I miss the product and that I wish it were still available.
Q And why is that? What did Prolift bring to your practice in terms of a treatment method for your patients?
A So the total Prolift was really very well designed for patients with severe apical prolapse or total eversion of the vaginal vault, and it prevented the need to have a robotic sacrocolpopexy. I feel like most of these patients are now forced down the road of robotic sacrocolpopexy or reconstructing transvaginally

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by fashioning a Prolift out of an Elevate, as I described earlier.
Q So when you described earlier fashioning a Prolift out of an Elevate for those certain group of patients, you're trying to turn other materials into a Prolift, aren't you?
A Correct.
Q Doctor, have you ever been paid more than $5,000 by Ethicon for your work as a consultant or as a preceptor? And by consultant, I'm not including litigation.
A It's a long question.
Q Sorry.
A But I've never been paid more than 5,000. I think the 5,000 is a very conservative number. I think it's more in the order of 2- to $3,000.
Q If you'll take a look at Exhibit 11. If you could turn to slide 34.
A Is that a page?
Q Yes, a page number. And this was the slide from Exhibit 11 on the FDA slide deck, and that slide is titled Organ Perforation and Injury; do you see that?
A Yes.
Q And do you recall the line of questioning that plaintiff's counsel asked you about the rates that are

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reflected on the right side of this slide?
A Correct.
Q Does this slide deck -- is the information in the slide deck limited to the TVT retropubic device?
A No. These are most likely all retropubic transobturator and mini-slings.
Q Well, let me restate. It wasn't a very good question.
And the line that is referring to retropubic; do you see that?
A Yes.
Q Does that indicate that it is solely related to the TVT retropubic device?
A No.
Q In the line on transobturator, is that indicating that it's solely related to the TVT obturator deviation?
A No.
Q In the transvaginal repair line, is that indicating that it's solely related to Prolift?
A No.
Q And am I correct that, based on your review of the slide, that the rates that are reflected on the right-hand column include the rates of all of the adverse events that are listed at the top of the slide

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which are organ perforation, organ injury, urethral injury, ureteral injury, bladder injury, bladder perforation, rectal injury, cystotomy, and enterotomy?
A Yes.
Q Can you look at Exhibit 13. You were asked about the Zhang article. And do you recall being questioned by plaintiff's counsel about this Exhibit 13, the Zhang article?
A Yes.
Q I'd like to draw your attention to the conclusion of that article on page 110 of the article and it's about halfway down, the conclusion. Am I correct that part of the conclusion of Dr. Zhang and the other authors is that, quote, "Despite the high incidence of long-term complications, most complications were not consequential and the patient's quality of life retained significant improvements in the long-term. Sexual function was unchanged by either procedure," close quote.
That was part of the conclusions made by Dr. Zhang and the other co-authors in the study, correct?
A Yes.
Q And is that conclusion consistent with your opinion and your review of the other medical literature

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on TVT and TVT-O?
A Yes.
Q If you could pull out your general TVT-O report, and turn to page 21. Do you recall being asked several questions by plaintiff's counsel regarding the Schimpf article and whether certain amounts of patients who were operated on with Gore-Text, skewed results of de novo urge in the context of pubovaginal slings. Do you remember that line of questioning?
MS. FITZPATRICK: Objection. Misstates the testimony -- the questioning.
A Yes.
BY MS. KABBASH:
Q In your report on page 21, the first full paragraph at the top says, "Alvo, et al., performed a multicenter randomized trial comparing outcomes in women undergoing autologous rectal fascial pubovaginal slings and Burch colposuspension. Postoperative treatment for urge incontinence was required in 27 percent of patients in the Burch group and 20 percent of patients in the autologous fascial sling group."
Are those outcomes, as reported in the Alvo study -- first of all, is this Alvo study also referenced as the sister trial?
A Yes.

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Q And are these outcomes that are reported here in your report, do they form part of the basis for your opinion regarding the relative risk of de novo urge among different surgical options to treat stress urinary incontinence?
A Yes.
Q The next sentence is, "Furthermore, in the AUA guidelines, meta-analysis for the surgical management of stress urinary incontinence, de novo urge incontinence occurred in a median of eight percent of patients undergoing the Burch procedure, nine percent of patients undergoing autologous fascial slings without bone anchors, twenty-eight percent of patients undergoing cadaveric slings with bone anchors, and six percent of patients undergoing synthetic midurethral slings twelve to twenty-three months postoperatively"; do you see that?
And was that important information to you in assessing the relative risk of de novo urge from different surgeries to treat stress urinary incontinence?
A Yes and yes.
Q And why was this information relevant to your opinion?
A These are gold standard studies that we've

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used over the years in using traditional surgeries for stress incontinence. And so that's where the range of up to 20 percent for de novo overactivity comes from and applies to slings as well.

Q Was Dr. Jerry Blaivas, in fact, as a co-author of these AUA guidelines?

A I think he was.

Q In your questioning by plaintiff's counsel, she asked you whether Prolift TVT and TVT-O can be a cause of dyspareunia, and I believe you said yes. Do you recall that?

A Yes.

Q In what way do you believe Prolift TVT or TVT-O can be a cause of dyspareunia?

A Well, just like any other anti-incontinence surgery or pelvic floor surgery, there is a risk of dyspareunia any time you're operating in the vagina near the pelvic floor or even doing a hysterectomy. So -- and those rates with prolapse, with TVT-O, with retropubic TVT, are all consistent with the same rates in traditional surgeries for anti-incontinence or for anti -- for traditional surgeries for incontinence as well as for prolapse.

Q As part of your report in the formulation of your opinions, did you review 8/20/15 Maher/Cochrane

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review on the treatment of prolapse?

A Yes.

Q And did the Maher/Cochrane review form a conclusion as to the relative risk of dyspareunia in vaginal mesh repairs as opposed to native tissue repairs?

A Yeah, let me get that out so I can speak without guessing.

So no difference in total vaginal length between mesh repairs and non-mesh repairs. De novo dyspareunia was no different between mesh repairs and non-mesh repairs. There was no difference even amongst the -- when they subcategorized it according to the extent of the repair, there was no difference in the sexual function questionnaire. There was no difference in quality of life between the two groups.

Q And, Doctor, is it your opinion that dyspareunia can occur following a Prolift TVT and TVT-O because of the fact that you were doing surgery in the pelvic space?

A That's correct.

Q And --

A That's one of the potential reasons.

Q And are you convinced that you can have dyspareunia from Prolift TVT or TVT-O because of the

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device itself as opposed to the surgery to implant the device?

A No.

MS. KABBASH: Okay. I don't think I have any more questions.

(Time noted: 2:28 p.m.)

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CERTIFICATION

I, DANA N. SREBRENICK, a Notary Public for and within the State of New York, do hereby certify:

That the witness whose testimony as herein set forth, was duly sworn by me; and that the within transcript is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 1st day of April 2016.

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DANA N. SREBRENICK, CLR, CRR

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